PCAST Report Workgroup
Draft Transcript
February 15, 2011

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good morning, everybody, and welcome to the PCAST Workgroup. This is a Federal Advisory Committee so there will be opportunity at the end of the meeting for the public to make comments, and since it is being recorded, just a reminder for the workgroup and committee members to please identify yourselves when speaking. In addition to the PCAST Workgroup, we also have members from the HIT Policy and HIT Standards Committee around the table.

Let's begin with a roll call, starting on my left with Art Davidson.

Art Davidson – Public Health Informatics at Denver Public Health – Director
Art Davidson, Denver Public Health, Denver Health.

Judy Faulkner – Epic Systems – Founder
Judy Faulkner, Epic.

Gayle Harrell – Florida – Former State Legislator
Gayle Harrell, State Representative, Florida.

Charles Kennedy – WellPoint – VP for Health IT
Charles Kennedy, WellPoint.

Deven McGraw – Center for Democracy & Technology – Director
Deven McGraw, Center for Democracy & Technology.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Larry Wolf for Rick Chapman, Kindred Healthcare.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Paul Tang, Palo Alto Medical Foundation.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Stan Huff with Intermountain Healthcare in the University of Utah.

Hunt Blair – OVHA – Deputy Director
Hunt Blair, state of Vermont.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Dixie Baker, Science Applications International.

John Halamka – Harvard Medical School – Chief Information Officer
John Halamka, Harvard Medical School.

Farzad Mostashari – ONC – Deputy National Coordinator for Programs & Policy
Farzad Mostashari, ONC.

Paul Egerman – Software Entrepreneur
Paul Egerman, Software Entrepreneur.

William Stead – Vanderbilt – Chief Strategy and Information Officer
Bill Stead, Vanderbilt University.

David Blumenthal – Department of HHS – National Coordinator for Health IT
David Blumenthal, Office of the National Coordinator.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Wes Rishel, Gartner.

Mark Rothstein – University of Louisville – Chair of Law and Medicine
Mark Rothstein, University of Louisville, School of Medicine.

M
... ONC.

W
… at Federation of America.

M
... Geisinger.

Anne Castro – BlueCross BlueShield South Carolina – Chief Design Architect
Anne Castro, BlueCross Blue Shield of South Carolina.

Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards
Chris Chute, Mayo Clinic.

M
... with Cerner.

Craig Mundie – Microsoft – Chief Research and Strategy Officer
Craig Mundie from Microsoft representing PCAST.

Natasha Bonhomme – Genetic Alliance – VP Strategic Development
Natasha Bonhomme, Genetic Alliance.

Judy Murphy – Aurora Health Care – Vice President of Applications
Judy Murphy, Aurora Health Care.

Cris Ross – LabHub – CIO
Cris Ross with SureScripts.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Liz Johnson, Tenet Healthcare.

Linda Fischetti – VHA – Chief Health Informatics Officer
Linda Fischetti, Department of Veterans Affairs.

Alice Brown – National Partnership for Women & Families – Director HITP
Alice Brown, National Partnership for Women & Families.

Adam Clark – FasterCures – Director, Scientific & Federal Affairs
Adam Clark, FasterCures.

John Derr – Golden Living LLC – Chief Technology Strategic Officer
John Derr, Golden Living, representing long term post-acute care.

Steve Findlay – Consumers Union – Senior Healthcare Policy Analyst
Steve Findlay, Consumers Union.

John Klimek – NCPDP – VP Industry Information Technology
John Klimek, NCPDP.

Gary Malick – ONC
Gary Malick, ONC.

Judy Sparrow – Office of the National Coordinator – Executive Director
… members on the telephone, Marc Overhage, are you there?

Marc Overhage – Regenstrief – Director
Yes, good morning.

Judy Sparrow – Office of the National Coordinator – Executive Director
Connie Delaney? David Lansky? Marc Probst? Scott Whyte?

Scott Whyte – Catholic Healthcare West – Vice President, Clinical Systems
I'm here. Good morning.

Judy Sparrow – Office of the National Coordinator – Executive Director
Good morning. Gary Marchionini? With that, I'll turn it over to Dr. Blumenthal.

Joyce Niland – City of Hope – Associate Director & Chair, Information Sciences
Judy, I'm sorry. This is Joyce Niland, City of Hope.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you very much.

George Hripcsak – Dept. of Biomedical Informatics Columbia University – Chair
And George Hripcsak.

Christine Bechtel – National Partnership for Women & Families – VP
And Christine Bechtel.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thanks, Christine. Thank you.

David Blumenthal – Department of HHS – National Coordinator for Health IT
First, let me thank Judy Sparrow for the ingenious layout of this room. It's the first time that we've had bleachers for a meeting of this type, so something new happens all the time at the Office of the National Coordinator. I also want to thank Bill and Paul for chairing the PCAST Working Group. The generosity of this community seems to know no bounds in terms of the willingness of people to donate their time and energy to the work that we call on them to do.

This is a terrific assembly of the talent that we have relied on for guidance at the Office of the National Coordinator, having most of the members of both of our advisory committees, our FACA committees, as

well as the folks we assembled to review the PCAST Report itself. We are hoping to get your advice and insights on the implications of the PCAST Report, which was issued in December, and which has captured the interest of the White House and set, I think, some goals for us that are both important and challenging. And which raise quite a number of technical and policy problems that will need to be addressed if we are to reach a shared vision of a truly interoperable dynamic, flexible capability for the exchange of health information in the United States.

The work that we are involved in here is, I think, somewhat different from what we've often been doing. It is in some ways more technical. You are being asked to look at the feasibility and approach specifically to creating a certain kind of architecture or infrastructure for health information exchange, and for the most part our work has been at a higher level. Though we've gotten deep into standards, we haven't directly confronted the question of exactly which infrastructure makes the most sense, and I think that calls for certain new additions to our technical expertise and I think we've managed to attract and draw on those sources for this and other deliberations.

It is very important, we feel, that the direction signaled by PCAST be widely and broadly discussed so that we can move forward with the support of the communities that must implement any recommendations that we go forward with. That has been one of the principles that we've operated on that we try to make sure that the ideas that come before us are processed in an open and transparent way so that there are no surprises and no appearance of arbitrariness, and a sense that a clear and deliberate process has been pursued. So I appreciate the willingness of Craig Mundie and the PCAST folks to come here and talk about their report. I appreciate the fact that many witnesses are going to testify or are going to be here sharing their perspectives. We promise we will look at all of this very expeditiously and come forward with recommendations for our next set of standards and certification criteria that make it as likely as possible that the vision that we share will be fulfilled. Thanks very much.

Paul Egerman – Software Entrepreneur

Thank you, Dr. Blumenthal. I want to first welcome everyone to our workgroup meeting, say good morning. Dr. Blumenthal, you thanked everybody and you were also very gracious in thanking Judy Sparrow who did indeed do a terrific job in putting together this workgroup on short notice. I want to tell you the entire ONC staff has been great; Jodi Daniels, Doug Fridsma, and Janie Skipper have all been extremely helpful, but I also just want to take a minute and thank you for your leadership. Your leadership as a national coordinator has been phenomenal over the past few years. It's hard to believe as much progress that we've made. This hearing is actually a reflection of your leadership in that we bring together stakeholders that represent very diverse viewpoints in our industry, to make sure that we hear their feedback and take into consideration the very real world issues that they are facing to make sure that whatever directions we set are consistent with what they need to do. So I want to thank you for that leadership.

PCAST: We say PCAST so many times sometimes I think we forget what it stands for, it's the President's Council of Advisers on Science and Technology, and it's an advisory committee that advises the president, so it's an advisory committee like the Standards Committee and the Policy Committee. PCAST published a report on December 8, 2010 and it was a report actually apparently requested by President Obama to evaluate the current status of HIT healthcare information technology. One of the things that that report suggested was that ONC (the Office of the National Coordinator) move forward with a sense of urgency, a number of places reported this, to act aggressively or to act boldly to move forward with a sense of urgency on a number of issues related to information exchange. As I said, through Dr. Blumenthal's leadership we decided to do exactly what the report said, so this workgroup has been put together very rapidly, we've been meeting intensely, and we have a goal of completing our work in the next two months.

These are the members of the workgroup team, as I start out and not able to handle the slide correctly, but that shouldn't worry you, you know this is a technical presentation. Basically, these are the members of the workgroup team and these people have introduced themselves, but as we said, this is a very

diverse group of people. Here is a brief discussion, just a description of the workgroup's charge. What we are trying to do is, as it says here, the first bullet is to really understand, synthesize, and analyze public comments and input to the PCAST Report. There was a request for public comments that ONC issued in the federal register on the same date as the PCAST Report was issued on December 8th and there's been over 100 comments submitted. This workgroup will be reviewing all of those comments and doing our best to, as I said, synthesize and summarize those. The second bullet is to discuss the implications of the report and its specific recommendations on ONC's current strategies. The third bullet is to assess the feasibility and impact on the report on ONC's program. So what we were trying to understand is well, there's a number of recommendations in the report, what is the feasibility of implementing them, what are the implications, and also are there alternatives that could be determined that would accomplish the same goals that perhaps would be easier to do. So that's basically what the workgroup charge is.

The last bullet on the screen says that we are here to elaborate on how these recommendations should be integrated into ONC's strategic framework, the strategic framework being a document that is included in the legislation that is reviewed, I think once a year with Congress. In other words, an actual strategic framework document and we will probably be trying to see how we can fold the PCAST recommendations into that document.

There are some things that we're not here to do. I want to be clear on that. There are some aspects of the PCAST Report that deal with CMS, which actually in my personal opinion is very good ... exists. Because it says if people are looking at this whole thing in what I would call a holistic way and viewing the entire system not just the healthcare providers aspect, but we are not addressing any of the recommendations related to CMS. Also we're not here to judge the PCAST Report or to criticize it or to make comments even necessarily about some of the things they might say about the current status of what healthcare information technology is. We're really here to understand what the recommendations say, what are their implications for what we're trying to accomplish right now. So that's what the workgroup charge is all about.

It's fortunate that the Deputy National Coordinator, Farzad, I hope I got your title right, Farzad Mostashari, so Farzad, do you have any comments ...?

Farzad Mostashari – ONC – Deputy National Coordinator for Programs & Policy
Sure. Just briefly, the question was asked what are the implications of the PCAST Report for ONC programs and policies, I just want to lay out, I'm the Deputy National Coordinator for Programs and Policies, so I want to lay out what some of those might be. You mentioned the strategic plan, and I think broadly, as Wes has pointed out, it's important to have a sense not only for the near term but also for the long term. What the implications might be for some of the aspects of our strategic plan, including not only exchange of health information but also the privacy and security framework, consumer eHealth in a learning healthcare system. Those are important long-term objectives that are part of the federal strategic plan that may have significant implications for it.

Then we move on to the policies, and quite specifically here we are again fortunate to have some deadlines and some timelines and milestones, the most important of which are the set of really linked regulations that we're going to hope to have an NPRM out before the end of this year for meaningful use stage two. As well as the certification criteria and standards that are associated with that rule, as well as governance rule for the governance of the Nationwide Health Information Network. So I imagine there may be significant implications, and in order to have the PCAST Report as part of what explains the very accelerated time frame for this workgroup, is for us to have sufficient opportunity to get public comment on the implications and options for integrating PCAST's viewpoint and vision into our regulations coming later this year. Finally, to mention our programs, our grant programs, cooperative agreements and grants, including particularly the state health information exchange grant programs, our Beacon community programs, and the SHARP grants, so those are the areas, policy and regulation programs as

well as long-term strategic view that we would be looking to receive input from this workgroup on. Thank you.

Paul Egerman – Software Entrepreneur
Thank you very much, Farzad. In a couple of minutes, I'm going to explain how we're going to be running the hearing. First, I want to find out, I'm fortunate to have a terrific coach here, Dr. William Stead from Vanderbilt, and I wanted to find out, Bill, if you would like to make any comments?

William Stead – Vanderbilt – Chief Strategy and Information Officer
Thank you, Paul. I think that as we have worked one of our clear challenges is to understand the key directions of this report, and actually to separate from those directions the examples of technical specifics that PCAST included to help us understand the directions. If we can tease those apart and then frame alternatives, then I think we will provide something very successful, and I think we have the minds at the tables to do it. So thank you, Paul.

Paul Egerman – Software Entrepreneur
Thanks. As Dr. Blumenthal said, we're fortunate to have representing PCAST Craig Mundie, who I think was co-chair of the workgroup that created the report. So Craig, would you like to say anything?

Craig Mundie – Microsoft – Chief Research and Strategy Officer
We were happy to work on this report at the request of the president for more than a year, and I look forward today to listening to the comments that come through this advisory committee's discussion. I'll be, along with Christine Cassel this afternoon, giving you an overview of the PCAST Report and some of the thinking behind it and then offering personal comments, as Christine will, about its evolution. Thank you.

Paul Egerman – Software Entrepreneur
I do want to say that I very much appreciate that you're here all day today and actually will be here tomorrow also for our discussions. I know that we set this up on very short notice and they told me you were supposed to be in India, and you were originally going to do a very fancy video hookup but you decided that this was important and you canceled your plans to be here, so I appreciate that. I know Christine also had to rearrange things; she was apparently a keynote speaker some place and changed that so that she could be here to participate also, so I want to thank you for your involvement in the process.

I'm going to explain how we're going to handle the hearing, and as I do that, I'm wondering if we can ask the first panelists to go ahead and sit down so that we can explain to them what we're going to do. If you look on the screen, what you see is the list of the panels that we'll be hearing from. The first thing I want to explain is that you should not infer anything from the sequence of the panels, that there's any particular importance that we're doing one in front of another one in a particular sequence. The sequence of the panels was determined by a little bit of the availability of the speakers, so there is some very difficult scheduling going on here and a little bit of juggling. We originally wanted to do patients and then providers, but we felt it was more important to get the right speakers here than to have the right sequence, so that's my first comment about the panel. We also have a lot of people here and so we're going to try our best to run this panel, the hearing with a clear sense about timing.

The goal of the hearing is to hear from various stakeholders to get information to understand what are the implications of the PCAST Report's recommendations and what is the feasibility, and because we have such a tight schedule and because we have so many people here, I want to explain to you, the panelists, how this is going to work. Each panel has a moderator and you will see on the screen that there is a timer. For each panel you have a specific amount of time to speak individually. For people in the morning it's five minutes, and the issue is that it's a hard stop at the end of that five minutes. A hard stop means that you have to stop. So if you're in the middle of a thought you cannot finish that thought, you have to stop and if you're in the middle of a sentence you can't finish the sentence, you have to stop. If

you're in the middle of a word, you can finish the word but only if it's short, it's like five or fewer syllables. It's a hard stop at the end of five minutes. If you go over five minutes, this guy, Farzad, writes your name down and I won't tell you what happens to you once he writes your name down, but you don't want to be on that list. So it's an absolute hard stop at five minutes for this panel. Just be happy you're not on panel number four where it's three minutes.

Those are the rules. Each panel has a moderator, and the moderator will handle the questions and answers. I know that there have been some people here from the PCAST Workgroup who are not familiar with how we do this, but the moderator, after the people speak, will make some comments of their own if they want and then we'll ask for questions. When they ask for questions you simply turn your name tag vertically, like this, and the moderator will call on you. We have a lot of people here, and it's possible we may not get through all of the questions. When we do our question and answer period, because we will adhere to the schedule, but if you have questions that are not answered, it's a comment to all the people here on the Policy and Standards Committee Workgroup, if your question doesn't get answered what we want you to do is to send an e-mail to Judy and a copy to Bill and me with your question. Make sure you tell us which panel and who it was for, and then we will get back to the panelists and try to get the information that you're asking for. We will not leave any questions behind in terms of how we will handle that.

So that's how we're going to handle the panel. The first panel is on health information exchange and the Healthcare Stakeholders, and the moderator is Wes Rishel.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Thanks, Paul. We have very distinguished speakers and when you come to "been there, done that," these are they. We have the largest single free submission and the smallest in this group, and we're just going to get right to it. Carol Diamond has been involved in shaping HIEs since they were called RHIOs, and Carol, would you like to begin?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Sure. Well, I'll point out that we never called them RHIOs. It's a pleasure to be here today. Thank you for inviting me. As Wes alluded to, my remarks today reflect the collaborative comments that we submitted to ONC in response to their request for information and I offer those as written testimony. In my verbal testimony today, I will just be highlighting a few points, emphasizing the importance of fair goals and a policy framework and also suggesting a research agenda to consider the implications of implementing novel technology approaches in a heterogeneous and complex environment like the U.S. healthcare system.

Let me start by saying that we really support the vision that PCAST laid out for creating the capacity to exchange health information securely using the Internet. And all the new networks using distributed networks for information sharing and on a national database using a model to linking patient information using existing identifiers and not a single national identifier, taking an approach to technology that emphasizes innovation and a diversity of solutions to support broad participation and new entrants. We also identify areas for further development and analysis based on experience with three foundational principles, and in my capacity in Markle Connecting for Health, which is a large public-private collaborative, we've been together nearly a decade, give or take, and much of our work, including the development of a common framework, was derived in some way from these principles.

The first is that a trust framework really is a framework and it needs to be based on a framework of fair information practices or FIPs. That any information sharing effort really needs a full complement of protections, clear and transparent policies, limitations on data collection and use, individual participation and control, oversight accountability remedies enforcement, in addition to technical and security protection. Trust can never be achieved by technology alone, and the challenge is really to find the right mix of policies, practices, and technologies so that information can be protected while it's capable of being shared with authorized parties who will inherently, for the foreseeable future, be at different stages

of technology adoption and sophistication. Similarly, the objective to give consumers greater control over their information is the right one, but no one policy can substitute for the complete framework of protections, and consent is an important element of a full complement of both policy and technology protections that must be balanced and applied together.

The second principle is that enabling greater information sharing through simple, progressive steps using well-tested standards and technologies and guidance by a policy framework is critical. We agree with the sense of urgency that PCAST laid out in wanting to accelerate the use of common exchange standards. We believe the pathway to this goal starts with the imperfect data of today in exactly the form that it's in, taking into account the wide variety of varying complexities in healthcare today, from sophisticated environments to small office practices. The challenge is to build from the simplest and most widely adopted solutions that can work in the real world today and I think is direct emphasized, starting with secure transport over the Internet, is clearly a priority area. We asked that ONC create a research agenda to further evaluate, including private projects and prototypes to further evaluate some of the innovative recommendations using granular metadata and granular permission controls catalogued and moderated by a few national DEAS'. We suggested the research agenda consider the following observations and reflections. Experience has shown that large IT upgrades or novel technology infrastructures and standards have high risk of implementation failure and that it's important to remember that a standard, even when perfectly developed and specified, does not have value in and of itself. In large, complex environments standards are not created, they are adopted. And ..., in my written testimony, is a very good example of that.

Second, I think it's very important that improving the reasons to share data, namely achieving quality and safety goals, create the incentive to improve data quality and adopt more standardization is something that specification of standards can never achieve on its own. There are lessons to be learned from DRM and P3P as well. On the issue of the index, we ask that some consideration be given to some of the policy driven recommendations we made in the ... common framework. While encryption is one key part of protecting metadata, it's not sufficient against some forms of breach such as attacks by authorized actors, which is a common source of attack, as we know now from Equifax SIPRNET.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Thanks, Carol. I'm going to at least ask one question. That will give you a little more time. Is Marc on the phone?

Marc Overhage – Regenstrief – Director
Yes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
You've got it, Marc.

Marc Overhage – Regenstrief – Director
Thank you. I cannot see the time run line, but I'll try to track, so somebody yell. Thank you for the opportunity to testify today to help synthesize and analyze the public comments and other input received relative to the PCAST Report. My remarks today are from the perspective of a large, vibrant health information exchange and its participants, and I'll try to complement rather than reiterate points made by the other panelists. Thanks, Judy, for sharing all these testimonies to enable that.

A basic goal of the report recommendations is to develop a technological approach which will increase the speed with which we are developing an interconnected healthcare information environment. A major concern this approach or implication raises is the proposed technologic approach does little or nothing that can't be done with today's established technologies at the risk of derailing progress. So I'm going to briefly describe a real world existing approach, our health information exchange, as sort of a counterpoint to the question of do we need new approaches, new standards.

The Indiana Network for Patient Care, developed by the Regenstrief Institute and operated by the Indiana health information exchange, along with our DOCS4DOCS clinical messaging platform, is a robust health information exchange that supports the movement of structured and coded clinical and administrative data among hospitals, independent laboratories, radiology centers, payers and others. With over 80 participating hospitals and approximately 1,500 interfaces today the INPC supports access to over 3.5 billion structured results, hundreds of millions of text documents and images, as well as genomic data for over 11 million unique patients in a federated, centrally managed system. Almost 20,000 physicians and their staff are connected.

Data are captured from a variety of source systems, laboratory systems, radiology systems, and so on, using HL-7 version 2 messages which are normalized. The metadata generated by these source systems are retained along with the data, and the patient demographics from ADT systems are used to create a global patient index, which uses ... deterministic matching to link patient identifiers without any reference to clinical data in a common way. This is analogous to the record locator service described in the Connecting for Health framework. The INPC exposes data, the Indiana Network for Patient Care, in a number of ways and formats. Systems and users can access data through HL-7 version 3 CCD messages, including through the Connect gateway, HL-7 version 2 messages in XML or pipe delimited format as structured, human readable documents, or through browser-based interfaces embedded in other applications. In addition, the source code for this system is publicly available through open source.

We've utilized this infrastructure to support patient care, healthcare operations, and research; in short, a learning healthcare system. For example, each month we compute quality measures for over 5 million patients in support of our Quality Health First program and these measures are reported not only to multiple payers, including CMS and to satisfy PQRI reporting requirements but also to individual physicians for quality improvement. As another example, emergency department ambulatory visits are classified into categories based on the reason for visit, and sophisticated surveillance algorithms monitor and indicate trends for disease outbreaks. I could go on with the other uses for research and so on, but I want to make a couple of other specific points about the technological approach and the practicality.

The report notes that modern network computers are particularly good at indexing, finding, and retrieving data that are discrete and close to the surface, even when the pieces are distributed widely over many computer systems and data source. I think the notion of close to the surface is a key challenge for current search technologies, and in fact surfacing the deep Web through approaches such as prototypical query construction continue to be a research challenge even for the most sophisticated technologic organizations. Since patient data are almost certainly thus natively stored in databases, the assumption that the data will be close to the surface has to be carefully examined.

The second point I'd like to make is that it's unclear to me how data normalization will happen. The assumption is data normalization will somehow happen at the edge, and while I think there is a role for late normalization of the data, many important uses of the data are inhibited if we are limited to normalizing the data when we retrieve it as opposed to at the time it is generated. Assuming my time's coming to an end here, I think the key takeaway for me is that redirecting a nationwide effort, and I contrast it with a federal or a national effort, is highly risky at this point. As the report acknowledges, we've achieved a degree of momentum. This momentum is really a remarkable achievement thanks to the Office of the National Coordinator, CMS, and the many other organizations across the country that have put their shoulder to the wheel. We've seen the damping effect of this type of redirection. A recent example has been the introduction of the CCR message format, which in our opinion has caused months if not years of—

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Marc.

Marc Overhage – Regenstrief – Director
... reversal. Thank you.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Thank you, an extraordinary accomplishment doing that line. Maybe we should cover up the clock for our speakers and see how that works. Art Glasgow is with Ingenix and brings, through Ingenix, a unique perspective because Ingenix is involved both on the payer side and the provider side of the house. Art?

Art Glasgow – Ingenix – Chief Technology Officer
Thank you, Wes. Good morning, everybody and thank you for the opportunity to represent the views of Ingenix on this important topic. First of all about Ingenix, we do believe that our view here is informed by a unique position of serving all of the actors in healthcare. We do serve providers, commercial payers, government, and life sciences, and we do so with the respect in a foundation for the use of data to improve both cost and care decisions, that is our legacy. Within the HIE space through our subsidiary Axolotl we currently do power the most number of state and regional HIEs, so this topic is very near and dear to our heart. At the risk of repeating some of what the other testimonies have already said, I just want to focus on a few points today.

I think the main thrust of the PCAST Report is that the use of a metadata tagging model in order to promote systemic interoperability is something that we do support. We are tagging data today within our HIE constructs for some limited uses, and we do believe that such a construct is consistent with promoting a wider degree of interoperability than exists today. However, we do offer that semantics do matter and there is such a thing as too granular, that taken to an extreme this approach can provide challenges to both patient safety and care, but marrying it with the current document approach that we have today maybe provides an answer. The current document based approach for interoperability today is designed to reduce variability and promoting that interoperability. I think that allowing that effort to continue, as ONC has led by marrying together this idea of data tagging within it, will allow us to maybe create sub-composable documents that will allow both the research use cases that PCAST allows and the transactional use cases that the current document based approach envisions.

In the area of cost and sustainability, we do offer a couple of thoughts as well. This is a fundamental departure, if taken in whole, from the current approach and will be costly across all ranges, both payer, provider, and vendor. We disagree with the PCAST Report in that new taxes should be levied on industry in order to pay for this. We fundamentally believe that it has to be rooted in value, value backed to all of the actors within a healthcare community, whether that be the provider space or the payer space. We do believe that there are sustainable models within health information exchange that would allow for this that are promoted and in fact improved by the PCAST effort. So we do encourage that ONC take a look at this from the standpoint of an end-to-end value chain from the data all the way from provider, including patient, all the way to the payer, and that it take a wider view of health information than just clinical information, the throughput to administrative transactions.

Wes, I don't know if my time is up.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I don't know either. The timer's not on the screen. Who has the time here? Oh, it's that. Keep going, two minutes, no problem. We don't give you any credit, though.

Art Glasgow – Ingenix – Chief Technology Officer
We encourage an end-to-end view, both from a value chain perspective and from a data perspective when taking a look at these recommendations. Then finally, in terms of what can be achieved in the time frame of 2013 to 2015, I think it's important to not undo what has already been done. There's been a great amount of effort and cost already placed into promoting interoperability at varying levels, whether that's through NHIN Direct, through what Marc spoke about within regional and state HIEs, and it would be counterproductive to undo all of that work with a drastic left turn. However, I do think supporting some of the tenets of the PCAST Report through the meaningful use program is reasonable and is feasible in terms of supporting document structure such as HL-7 v3 CDA that already supports some of this concept,

as well as supporting efforts like NQF Healthy Measures. And driving the value of taking such an approach to tagging data to something tangible and fungible, improving quality through the measures, and being able to drive this information in the workflow. Thank you. I look forward to your questions.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Thanks. Marc, while we still have you, I had one question for you. I think what you were portraying was pre-normalization as a value added by the health information exchange. Does that sound about right?

Marc Overhage – Regenstrief – Director
The key point I wanted to make was that the data generated by today's systems, laboratory, radiology, and so on, needs to be normalized early in its life because those systems are very dynamic. Not the format so much, but the content: new laboratory tests, new provider identifiers and so on. The experience across the country, Santa Barbara, Indianapolis, and many others, is that normalizing the data, expecting the source systems to normalize the data has not been achievable, partly because they do not have the insight and understanding of the national terminologies and vocabularies. While I think we all expect that the trajectory is that those should be embedded as the primary codes and primary tools in these source systems, that's a decade down the road.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Thanks. Does this approach of early pre-normalization lead us to difficulties in re-normalization as our understanding of the data grows? Is it scalable? Where does that value come from on a national basis?

Marc Overhage – Regenstrief – Director
Two things, to answer your first question, as described in our written testimony, you obviously want to keep the method data, if you will, the original code that's laboratory generated and has ways to do either lazy mapping later or to do revisions, if you will, as you learn more in the future, so there's no question about that. But it's important to normalize up front if you, for example, want to drive clinical decision support to trigger events for the patient based upon a result generated if you want to do public health reporting of electronic lab results. If you want to do reporting of syndromic outbreaks, you really need to know when the data are generated and what they are in order to be useful.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Carol, I just want to note that your testimony raised issues about how well equipped the digital rights management technology is for particular issues dealing with healthcare. I'd like to ask you a question, though, and that is, where does the responsibility lie for protecting healthcare data? Is it everyone, which might mean no one, how do we account for that responsibility in a national point of view?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I think the point of using the digital rights management example is that it's an example of tagging a permission to the content. Any kind of tagging isn't compliant, right? You can have a tag in metadata that says something, but you still need a person to implement the right behavior or policy to fulfill the instruction of that tag. The particular DRM issue, though, is another one I think that is also important, which is to say that the DRM approach proved not to really prevent piracy of content, but it did prove to put restrictions on legitimate use of content and potentially couple content to hardware or for innovation. I think that is a cautionary tale from DRM.

In terms of whose responsibility it is to protect information, I think the answer is everyone. That is the purpose of a framework. Everyone who holds a person's information in the healthcare environment has a role in protecting the information that they hold. In fact, one of the reasons we emphasize trust so much is that we believe that trust is not an attribute of data or technology, it's an attribute of participants and entities, therefore, it has to come about through participation and trusted experience.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

Thank you. I'm looking for cards up from the PCAST group originally and then from those in the two workgroups, two committees. Dixie?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I had a question for Carol. In your written testimony, you talked a lot about the need to restrict DEAS to make sure that it didn't include clinical information in its metadata. How do you propose to define clinical information such that none of the metadata really can disclose identity of individuals in the metadata?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
The distinction we made in the Markle comment framework was to say that any metadata that is disclosing clinical information—not identity or demographic information—should not be there. In other words, it should not be kept from the index. Again, the reasons for that I go into in the written testimony, but the idea of centralizing that clinical data or metadata creates risks or exposures. It's not, however, a reference to the identity or demographic data.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
So is a person's age, which I would consider demographic, is that clinical as well?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Well, look, we didn't go through and say what categories of demographic data are important, but to the extent that any piece of metadata like, for example, in the record locator service you might look for records for me and the record locator service would say records for you are located at General Hospital. It won't say General Hospital has lab type records or pharmacy type records or x-ray type records. In other words, the kind of information that speaks about the clinical information is something that an entity holds. I wouldn't parse on just some demographic issues. The point is that the clinical information could be disclosing and the metadata about the clinical information could be disclosing.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
And you think the PCAST Report is proposing to include clinical information?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
No. I provided that as testimony because it's a discipline we have in the common framework. I don't know what metadata is included. There are some examples given in the PCAST Report, but I think that's very much a subject of further discussion. I'm just suggesting that as a policy driven approach to what should and should not be included in an index that sits on the network, that we advise against using or providing clinical data or metadata in that index because breach is catastrophic.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Carl?

Carl Dvorak – Epic Systems – EVP
This is a question for Marc Overhage. You commented that many of the technologies that we need for health information exchange have been designed and are in successful use in the Indiana Exchange. But you argue that doing things at a national level was risky. I wonder if you can comment on whether you think that the technologies that you're using are or are not scalable to a national level.

Marc Overhage – Regenstrief – Director
Thank you for the question, Carl. I think that the technologies are equally scalable to a national level. As I pointed out today, we are supporting over 10 million unique individuals' data with a fairly simple environment, and we strongly believe that there are direct paths to continue to scale that. Not in a central way, of course, because I don't think anybody believes there's a central scalable solution.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Who's next? Stan?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
One of the things that the PCAST Report said, and then you reiterated, Carol, was that this could be done without the use of universal patient identifiers, and I think that's true. The question that seems to not be asked is actually the best way to do it. All my experience would say we would actually be much more efficient if we had patient identifiers, and I've always been confused by the assertions that not having them is somehow more secure. Because if the goal is actually to share across enterprises information about individuals and link that individual across enterprises, if you don't have the identifiers then you're forced to send the information you're trying to protect in order to do the match. So if I don't have the identifiers then I'm forced in some way to send name, address, age, birth date information in order to make the match across the institutions. So while I agree that you can do it without patient identifiers, I'm wondering what the motivation is to do it without patient identifiers, because it seems much more efficient to do it with patient identifiers.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Yes. So for many people sitting around the table you all know ... terms this is a "been there, done that" question for us because we spent an entire year on this issue in 2004-2005. Let me say one thing about the assertion that you're forced to send information that's potentially exposing. The index doesn't give you any information you don't already know and nor does it have to expose it to anyone else you're trying to match with. It simply gives you the location of record. So if you didn't know the patient, the correct spelling of the last name, the index doesn't give you the last name back, at least that's the way it's done when it's policy constrained. We did an entire 80-page paper looking at the issue of whether or not a unique identifier was the right policy approach. Our conclusion was that it was not, for a variety of reasons, not the least of which actually was a simple implementation question, which is to say even in countries where it's been available it's taken a very long time to implement.

The second was we learned a lot about why matching and linking of information is wrong in those days, and I would argue it hasn't changed, and a lot of that has to do with poor data quality. There was no reason to believe that yet another data field, which any identifier is, would not be subject to the same kinds of risks and inconsistencies and interposed digits and shared numbers and all the other things that we currently have with any demographic field that exists.

Then finally, just as you're saying, the identifier does represent a single key potentially to open every lock, so if you have that, and this is obviously what we've learned with SSN in this country also, when you overuse an identifier it ends up having unintended consequences. So for all those reasons, and I'd be happy to provide the committee with reference to the report and even some of the data that we tried to put in it looking at just accuracies of information, which if memory serves me correctly Dr. Halamka provided some of this data, I'd be happy to provide that to the committee.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Stan, did you have any more questions there?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
No, I guess just to say I'm not persuaded, but I understand.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
That's all right. I've been at this for a long time.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Paul?

Paul Egerman – Software Entrepreneur
I have a question for Marc. It's a bit about your model, which if I understand it right you keep each organization's data separate, in separate vaults. So when the physician does an inquiry they're able to

look at data across all these different organizations or across organizational boundaries. My question is, do you have any challenges with what I would call duplicate data, where data, like laboratory results or medications, are duplicated in more than one of these organizations? Is that a challenge and is that something you normalize for?

Marc Overhage – Regenstrief – Director
It is a reality of the world that you will see the same data represented in multiple ways for multiple sources. A real world example is a pharmacy dispensing record, a PBM record, and a payer claim record for a medication being dispensed at pharmacy X for patient Y, you will have the same clinical event represented in multiple ways throughout a healthcare ecosystem. The two key things to deal with that, at least our approach has been, number one, curating the provenance. In other words, making sure you know where the data came from and being able to make those inferences that ah, this is the dispensing event that relates to this PBM record, that relates to this claim, that relates to this prescription that Dr. Smith wrote. It sounds a little bit like Dr. Seuss or something. So you do have to deal with that. That is a reality of the world. The data will be replicated in a personal health record, it will be replicated, and so you simply have to manage that replication and you have to attempt to identify what are exact duplicates and what are similar but not duplicated data.

Paul Egerman – Software Entrepreneur
That's helpful. So if you look at what you're doing, Marc, and compare that to the write up of the DEAS', I guess people call it the DEAS, in the report where it appears that there's none of this normalization. Do you have any opinion about whether or not this duplicate challenge makes the DEAS less usable or is this a big problem? How do you view this issue?

Marc Overhage – Regenstrief – Director
Well, I think that's the area that has more thought and evolution in, but if the data are not normalized on the front end, it's very difficult to know. You can't know what the data are and in my testimony I describe the scenario of trying to do a "simple quality measure" and trying to find the patient's most recent LDL cholesterol value. I think if you don't pre-normalize those things that you essentially have to touch every source of patient data and every bit of data in that source in order to find the most recent cholesterol. That both poses, it seems to me, a real efficiency challenge as well as a very large privacy issue, as Carol described in her testimony, of do I really need to know about that HIV test. Well, I don't, but I've got to figure out whether the cholesterol test or not if you don't deal with that up front.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Marc, in your HIE there, how often do you actually go back to source system for data rather than go to some database that stands as a proxy for the source system?

Marc Overhage – Regenstrief – Director
Wes, I think you were the one who coined the term that we sometimes use of "edge proxy" for the state of representation, and we essentially never go back fully to the source system, partly because the source system sometimes ceases to exist. When you've been doing this for 30 years, the laboratory goes out of business, the physician practice disappears or merges, people adopt a new information system and don't carry forward the old data, so we almost never go all the way back to the source system. It's partly for those reasons that I just commented on, but also for efficiency. Can you imagine doing 5 million patients' quality measures with over 8,000 unique data elements incorporated into that run every month?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes, I think that there is a thought here that the techniques that are used to index the Web now and create centralized indexes changed the efficiency measures. Do you have any comments on that?

Marc Overhage – Regenstrief – Director
Clearly, you can index efficiently. The real question is can you retrieve efficiently. What do you do when the physician's office system is off line for a day and a half because they are a dial up Internet connected

organization? Or what do you do when the response time from the large health system is literally eight minutes because their systems are busy. It is not very feasible to harvest the information in that way at scale, nor for direct clinical use where clinicians will wait maybe three seconds, maybe, and any longer than that and you're dead.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Eileen?

Eileen Twiggs – Planned Parenthood Federation of America – Director
This is a question primarily for Carol, but I'd be curious to hear if Art or Marc has actually wrestled with this in implementation of an HIE. I appreciate what you said earlier about metadata not containing any clinical information, and I fully support that. I'm curious if you have considered and come up with a solution for the circumstance when by virtue of disclosing where that information is held you really are disclosing information about the care that's provided; Planned Parenthood obviously is my perspective.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Yes. In fact, that was the example that was invoked many, many times when we were developing the common framework. I think what's important to remember about at least the way the Markle Common Framework works and why we made some of the decisions we made, was that the reason for having a distributed network was to leave the decisions as close as possible to the entities that have the relationship with the patient. Because they were in the best position to express that person's desires or needs in terms of how information is shared. That information sharing is a decision. It is not a mandatory requirement. So, for example, when the name of an institution is disclosing in our model our assumption is they are not participants in the record locator service, in other words, they do not participate in an automated index, it's the nature of knowing that somebody's information is there can be so disclosing to the patient. Those are the kinds of policy decisions that need to get made and that should be made by entities who hold very sensitive information. The patient can always say to a provider, I have records at Planned Parenthood, or I was at Planned Parenthood and you should get my records from there. But the idea of automating that in an index is a policy decision because it is disclosing that we never assumed you could overstep with technology.

Eileen Twiggs – Planned Parenthood Federation of America – Director
So if I understand correctly, that would really require a manual opt-in process for the patient in the context of sensitive care?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
That is certainly one way to fulfill that.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Seeing no questions directly from the team, let's move to the broader group. Charles?

Charles Kennedy – WellPoint – VP for Health IT
When we've tried to make use of health information exchange using the clinical data to, let's say, automate UM to incorporate clinical data into case managers' or disease managers' systems, we've been frustrated by what I'll just sum up as the nightmare of HL-7. That's led us to a belief that semantic interoperability is what we've got to get to as quickly as possible. So my question for the panel is, do the two approaches, PCAST versus where we're headed now, do you believe there's an advantage to either to getting to semantic interoperability as quickly as possible? Or, does it not matter?

Marc Overhage – Regenstrief – Director
I'll take a first crack at that, and it's good to hear your voice, Charles. The format in which the data is represented is the least of our challenges. Whether it's HL-7 or CCD or something else is the least of our challenges. Stan has been a great champion recently, well not even recently, for a long time of helping us understand, and Wes actually blogged about this a day or so ago, how this information comes

together, how it gets integrated, what it means. The format and the way that we retrieve this data is not going to change that issue. What does it mean when somebody says that the patient has an allergy to codeine, or worse yet to Benadryl? What does that mean? Well, the format and structure of the data isn't going to help us there.

M
I would absolutely agree. I think semantic interoperability is needed under either approach and it is the biggest challenge that we have today. The concept of tagging the data at an elemental level can potentially help that, but it can also make it harder if we get too granular. So data in too small of chunks begins to lose its context, and I think how we as an industry and we as an organization choose to define that should be standard across our entire nation. That is where I think the greatest benefit can come from some of this work, is marrying the current approach with the ideas in the PCAST Report to standardize exactly that topic.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I would just briefly say that I think it also offers a cautionary tale on standards, which is that sometimes increased complexity, although well intentioned, results in either poor adoption or inconsistent implementation and the tradeoff is not one that we should be making. I know as a member of the Standards Committee, we have adopted some principles that try to write for the little guy, but the standards need to be simple enough that in the least sophisticated technological environment that you can see widespread adoption because any adoption at that level is incremental progress over where we are, over phone in facts.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
One last thought on that topic, in that it's not an all or nothing concept here as well. There are places that we can start with this idea that make sense, maybe those are problem lists, allergy lists, or medication lists, that are routinely traded, that can be composed into documents but decomposed from them and also traded individually. Marc, it sounds like you and Charles may have had some conversations about the nightmare of HL-7 before. To what extent is that related to what we were talking about earlier of normalization as a service, as opposed to normalization at the source?

Marc Overhage – Regenstrief – Director
I am not 100% sure. If you're asking the question does normalization have to be done in a source system, like a laboratory information system, or can it be done elsewhere? The answer is clearly it can be done elsewhere. But it requires in-depth knowledge of the source system, and this is one of the fundamental challenges that we face, that somewhere that knowledge has to get embodied. I'm not sure if that's what you're asking about.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
You talked about normalization as part of the process. I know that you've made that a part of your corporate business, the value you add is normalization, and I also know that you found techniques for doing that, right? Not to lead the witness, but has there been a reduction in the amount per lab interface it takes you to do over the years?

Marc Overhage – Regenstrief – Director
I'll follow you anywhere, Wes. The first premise I think is somewhere, somehow the work has to get done of mapping or translating local terminologies to standardize terminology so that you can move towards semantic interoperability. It's got to happen. It can happen at the source. It can happen in middleware. It can happen centrally. It can happen on retrieval conceivably. But you still have the same heavy lifting no matter how you do that of figuring out that code number A73 at this laboratory represents a serum porcelain level. In terms of have we made progress on that? Absolutely. We have certainly both decreased the time, I think our record recently was three weeks from start to finish for a sophisticated health system suite of interfaces, including the mapping of terminologies, and we have certainly gotten smarter about which terminologies to map.

The LOINC Team, for example, has continued to build more sophisticated tools to assist with that mapping and translation. I think the PCAST Report contemplates this kind of approach, as well as the ability to do what I call lazy mapping, which is getting close so that you can expose it to the clinician at the appropriate time but you might not get it to as fine a grain level for that literally 80% of laboratory results. Laboratory is the big mapping challenge. Radiology, they name things very well, their CPT-4 codes are usually handled, medications are not the big mapping, laboratories are the big mapping challenge, the volume of documents is modest, so it's laboratories that you really sweat. Clearly, there are three or four streams of development that I think have dramatically decreased the cost and time over the last three years of building those interoperable interfaces to laboratory systems.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I'm glad you made the point because I wanted to just emphasize that the notion of middleware, particularly as an interim solution, might be regarded not only as a piece of software that is the middleware, but as a service that is making the middleware go. I'm not leading the witness here. I'm just saying that on my own, Marc. Thanks.

Carol, did you want to comment?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Yes, I just wanted to use the opportunity in this discussion to make the corollary point. Which is that much of what Marc is referring to and that you're asking about is also not just in service of pure HIE, but in service of I think a very important vision that's in the PCAST Report about using distributed networks for population health analysis and quality measurement and research. I would just offer that Marc is clearly a pioneer in this area, Dr. Platt, who's here also, clearly is as well, and more needs to be understood and invested in research methodologies that answer some of these questions. I would argue not just about where the data gets normalized but how it does result in composite structures for those kinds of analyses.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So as we present alternatives we may consider specifically engaging in that area of the process of normalization.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Yes, in my experience when we really delved into this issue people like Marc and Rich and others who were doing these kinds of distributed analyses of population health issues are pioneering—I don't want to speak for them, but there are also a lot of unanswered questions. And a lot of research methodology that still needs to be developed to really make this a robust approach to answering some of these challenges, and more importantly, to not requiring the collection nationally of information in order to answer these questions.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Deven, you've had your card up and down, did you—?

Deven McGraw – Center for Democracy & Technology – Director
I did. I think I'm going to ask it off line to when the witnesses—

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay. Kevin—I guess I should be saying last names for people listening—Kevin Hutchinson?

Kevin Hutchinson – Prematics, Inc. – CEO
I want to come back to the national provider IDs and identification in general. We've talked a lot about normalization. But going off of what Stan was saying before, in building out a national network in a non-federated, non-centralized model, which I would agree with, the challenges we ran into was the ability to

actually get an exact match because the source code had such bad naming, misspelled last names, middle names, things like that. We know that putting aside the political debate about a national patient identification system, when we try to pull up from a provider standpoint the same issues with naming and other things, but when we had the DEA number and license number we were able to do some better matching. I would argue that concocting a first name, last name, address, date of birth, sex and things like that, that's the most well-known information on the Internet that anybody can get. You now have someone's ID in which to be able to match records, but what's been the panel's experience in dealing with source in a non-federated model, in dealing with source data to get an accurate match and not leave a large percentage of data on the table?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I would just say that nothing in the testimony or in the PCAST Report or in what I said refers to the provider identifier, which is well underway, and as you know, a very important part, I think, of making the infrastructure work. On the patient side, when we looked at this issue I will tell you the thing that stood out most in my mind was listening to people who managed large systems of population scale data, and certainly your formal organization was one of them. We grappled with this in Katrina health as well, the thing that stood out in my mind is this principle that became called the "cleaning up for company" principle. Which is to say that for most organizations cleaning the data falls pretty low on the to-do list, or improving the source system intake until the data's exposed, until somebody actually needs to use the data, other than the operational system in which it's potentially being collected. Then you do see incremental improvement in both policies and practice for the way in which information is collected and also maintained.

I think what's interesting over the last couple of years in terms of having direct access to consumers, if you look at the way the credit bureaus are working, it's your opportunity to fix your own data in many instances there. They amass the data about you, but there's a level of transparency and there's this user involvement in fixing that. I do think, though, this is wrapped up in a larger challenge of it's not just the identifiers. It's all of the data that needs to be used for clinical purposes and administrative purposes. That information exchange and information sharing and uses and valuing those uses, as Art said earlier, placing the proper motivations and incentives on how that information needs to be used to improve quality and safety, is what has the back stream effect, if you will, on making sure that people are paying attention to those systems and processes. I think most large organizations will tell that story.

Art Glasgow – Ingenix – Chief Technology Officer
I like Carol's characterization of cleaning for company. We do that within our HIE constructs today, so when we identify ...errors or misspellings we provide a report back to the provider organization that shows them how they need to clean up their source data. But also at the edge using middleware, this is an actual example of how we are tagging data today, when we get that match and we know it's the same patient we are tagging it with a unique ID within the construct of that specific HIE. So we're creating an index to improve that signal to noise ratio for future use cases so that is very similar actually to what PCAST is talking about in creating a DEAS within the HIE.

Marc Overhage – Regenstrief – Director
If I can just add a cautionary note about that approach, though, is that the fundamental demographics of patients sometimes magically change. We have a physician group and a hospital who war over a certain group of patients' gender, for example, and depending on which gender they are they may or may not match. So you run into some interesting challenges over time and over space because of the fact that not all providers will agree about even the simple data elements, which is very interesting.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I'm going to guess that this war doesn't have anything to do with the actual medical history of the patient?

Marc Overhage – Regenstrief – Director
Correct.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Cris?

Cris Ross – LabHub – CIO
Thank you, many excellent comments. I'll choose to focus on one, and, Art, if I may, I'll address this to you. I strongly concur with your notion that context needs to be maintained and your assertion that a way to maintain that is through document centric meta standards, CDA being among them, CCD and its ilk. I guess I wanted to pose to you, to what extent do you think the document centric approach is actually optimal given that many data elements and data types fit in that framework, awkwardly at best? Whether the alternative is to say, well, okay, for documents we can have document standards but, heck, what's wrong with the notion of a contextual meta standard that is not document centric but in fact gives us the level of granularity appropriate for the use case, and of course Stan's clinical data element models come to mind. Were you literal in your sense of meaning document centric?

Art Glasgow – Ingenix – Chief Technology Officer
No. My comments were meant to convey exactly what you're saying, that the current approach is not optimal from a technology or a data perspective, but it is being adopted and it is improving interoperability today, so we should not abandon it. We would take a step back if we were to abandon the current approach. However, looking at it from the standpoint of those documents being sub-composable in the contextual data elements, I think is the right way to approach this. So as we begin to merge these two efforts, there's no reason why we can't take a look at sub-document level data elements being tagged with context that can then be composed into documents that are computable today and some point in the future maybe not have a need for those documents.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I'd like to follow that up for just a second. I talked to a lot of physicians, and Lord knows they have a lot to worry about, but one of the things they really worry about is data that is composed and presented as if it was a physician's letter or a physician's document or something like that. Not only is there a danger of creating inferences that weren't there, but when something goes out under their signature they want to believe that they have selected exactly the appropriate data and left out the meaningful drivel that they had to do as interns and medical students and got right to the point. So is it the case that we're overloading the document with too many uses right now?

Art Glasgow – Ingenix – Chief Technology Officer
Yes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay. David's got his card up. He may want to comment on this particular issue as well. I'll let him ask the question and make a comment if he wants to.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Yes, Cris and Wes, that was my question. I was going to address it to Marc, so I'd like to get Marc's feedback on it. To restate it, the distinction between manipulating discrete results that have been extracted or were actually produced as discrete results, contrasted to or set alongside of the value of the documents that actually tell a story and wrap the context of a particular patient care episode in that document. So my question is going to be to Marc, because in Indianapolis you have experience with dealing with both of those domains pretty well. I would be curious to know what your feedback is from your clinician users, Marc, about the relative value of the document repository versus the discrete results in the flow sheet displays, and then certainly anyone else who wants to weigh in on that.

Marc Overhage – Regenstrief – Director
I think, as with many things, it's not an either/or. Clearly, as was being suggested, a clinician should have the opportunity to review and correct anything that is going to be asserted as their work or their

information generated. You shouldn't magically do that behind the scenes and surprise them with what information something contained that's attributed to them. On the other hand, when you look at large volume of actionable patient information, laboratory results, medication histories, the result of a radiographic study, things of that nature, many, certainly not all, many have meaning outside of a particular context. Clearly, a physician's note and the verbiage in that note, there are subtleties as we document our care of patients that we try to reflect, we try to craft. Frankly, I think some electronic health records have reduced our ability to do that because of the structured approaches that we drive clinicians to, but still we try to capture that.

I think that there are both. There is huge value, and in fact if we're going to realize the promise of electronic medical records and health information to improve the efficiency, quality, and safety of care, we must treat the data as discrete. If we want to do clinical decision support, if we want to do clinical effectiveness research, if we want to do public health reporting, we must treat this data at a molecular, as Wes coined it, or atomic level. But there are certainly some elements, some kinds of information that are best left in their context, the subtleties or the nuances of a radiographic interpretation, for example, might need to be viewed purely in the context of the full document, the full report. So, as you say, we mix those and try to use them appropriately.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Jim?

James Walker – Geisinger Health System – CHIO
I'd just like to add ... to that. Many, but not all clinical documents have a profound intellectual structure, the History and Physical is one, and the Discharge Summary is another classic. That structure embeds an enormous amount of grounding, of implicit knowledge, and the structure of those notes guides and supports information creation on the clinician's part as well as making it easier to communicate information. So the information in those notes really is highly context specific and even the data elements that are less context specific, like lab results and radiology results, the interpretation of those less context specific data or information sets often is critically dependent on the context specific information in the note. For example, clinicians almost never send a pre-test probability to a lab or a radiologist. The note, a good one, contains an expression, often hard to capture in anything except natural language, of that pre-test probability that determines the interpretation of that less context specific data. So we really do need both and we need to know more about how to express the relatively context free data in ways that links back to the clinician's pre-test probability, just as one obvious example, so that the document and the context free data really are linked in a way that other clinicians can make sense of them.

Paul Egerman – Software Entrepreneur
Just to ask you a question, Jim, I appreciate what you just asked, but could in the context of figuring the terminology using a PCAST Report, could you view the entire discharge summary, for example, as the data element, or an entire progress note as the data element as a way to get, as you call it, both?

James Walker – Geisinger Health System – CHIO
Yes, some kind of articulated information set, is the way I would say it, but yes. But the critical thing is that the interpretation of those depends on enormous grounding.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay, I'm getting close to having to cut this off. Larry hasn't asked anything yet today, so I'll let Larry go and then I'm going to sum up.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
One question that may open a whole round of discussion, so I'll put that out there as an initial thought and then a couple of other quick comments, in some of the written testimony there were comments about the importance of actually tying all this information in to usable workflow, or usable decision process. I think that's a really important point that we shouldn't lose sight of because the possibility of overwhelming

people with just data is ever present. We have lots of examples of that. To actually get it in a useful way so that it's actually helpful and not just increases peoples' anxieties about they're going to miss something actually needs to be addressed as we go forward. If we only look at the data piece here, we're likely to miss that part.

The other piece is this whole discussion about what's sometimes called a notion of fail soft, that we actually need to be set up to allow for failure. Most of our systems today do not allow for failure. They assume once they've established the patient identity, the patient identity is right. Then they bring the data in and then subsequently it's discovered that some of the data has inaccurately been brought in to a system. Finding it and pulling it out is close to impossible, and somehow notifying the users who might have seen that data that it has been pulled out also raises lots of problems, that our system's not set up for that. So a point of preserving context, it's a tiny example but I think it's telling, in the INPC flow sheet that a couple of folks mentioned already, when the data is presented back the primary axes are a test and columns by time, but the data also has a small tag that says where it came from. So in a relatively non-intrusive way the user is provided with context of this lab result, these lab results over time may have come from multiple labs, so variation might be more between the labs than within the patient, but you can see that if you have a question it's very easily available.

So I think we need to work on improving the sophistication of our systems as well, that one of the evolutionary challenges to the technology that's in place today is its assumption that things like the labs are all from one lab, the patient is always one patient, all the information all came from within my own system. That we're entering a world of multiplicity and we need to start to build that sophistication throughout our technology base, and that that's a very non-trivial problem and it's going to require a lot of enrichment in how the systems internally handle metadata and get out of this assumption being monolithic.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Thank you, everybody. Paul, you're going to screw up my schedule. Go ahead, Paul.

Paul Egerman – Software Entrepreneur
We've done a lot of talking about concepts and philosophy and policy and I thought a concrete example could help maybe gel it. One example is diagnosis. It seems like a very straightforward concept. I'm going to mention different contexts for that word. One is the diagnosis on the problem list. Another is then counter-diagnosis as written by the clinician in the note. A third is the billing diagnosis. A fourth is associated diagnosis for a lab test. Another is the diagnosis for rule out and it's an indication for a radiology procedure. Another one is a diagnosis that's arrived from, let's say, lab data like diabetes. All of those different diagnoses to the clinicians have a very, very different competence in terms of what it represents. Then to go back on what Jim said in terms of in another bigger context, one of those pieces of diagnoses in the admission note is going to be very different from the discharge summary. So as an example, that relatively simple concept, when I said it first, diagnosis can have lots of different meanings that are so embedded in the context, small or large.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Thanks, Paul. That was definitely worth taking the time for. I appreciate it. I think overall we'll summarize tomorrow.

Since I'm out of time, Paul, I'll just turn it back to you, or do you want me to make a few comments? Okay. I think what we're hearing is we're on a path from improving the flow of information in the course of giving care where we think if we haven't solved it it's tractable. We're optimists towards making use of the information as collected to do more that happens inside an institution when they begin to change their practices, reduce their variance in essence across a region, across society, and we're looking at that challenge and what it would take to get there. Some of the notions we've heard are the need to come to take the date where it is, that is to not assume it always starts out in perfect form.

We've talked about various ways of normalizing it for comparability and renormalizing it as our concepts change. We definitely are wanting to question the notion that every source system for data will be a good network citizen, that is to say that we'll still be there when you want the data, that it will be responsive and so forth, and want that to be part of our considerations. We are seeing any one of a number of instances where the benefit of extracting small amounts of data from encounters needs to be realized and at the same time needs to be balanced against the danger of oversimplifying it and losing context. That there's no clear path to that yet, that's part of the work that has to be done. Thanks.

Paul Egerman – Software Entrepreneur
Thank you, Wes, great summary and a great job. So thank you very much, Wes, and thanks again to the panelists, Carol Diamond, Marc Overhage, and Art Glasgow. I very much appreciate your efforts.

The next panel is a panel called Patients/Consumer/Privacy Advocates, and it's going to take us just a few seconds for the panelists to come forward. It is going to be moderated by Mark Rothstein.

Mark Rothstein – University of Louisville – Chair of Law and Medicine
Good morning. We'll wait for all the members of the panel. We are fortunate this morning to have four experts to address these very important issues. Let me briefly introduce all of them at once and then we'll proceed with their remarks. First, Donna Cryer, the CEO of CryerHealth Patient-Centric Solutions; second, Deborah Peel, Founder and Head of Patient Privacy Rights; third, Joyce DuBow, Senior Adviser, Office of Policy and Strategy, AARP; and finally, Lee Tien, Senior Staff Attorney of the Electronic Frontier Foundation. I want to remind you that the same ground rules are in effect as were in effect for the prior panel, that you've got five minutes and it's enforced ruthlessly. At the end of the presentations, we will have questions and I'm sure it will be a lively discussion. So we'll begin with Ms. Cryer.

Donna Cryer – CryerHealth Patient-Centric Solutions – CEO
Good morning and thank you for inviting me to testify before this committee today. I am an attorney and have served as patient advocate since my own liver transplant 16 years ago. I'm privileged to serve as a patient representative to the U.S. Food and Drug Administration, and to be a member of the Board of Directors of the American Liver Foundation; these remarks, however, are my own.

I want to applaud the committee for its excellent report and overall support the recommendations therein. My comments today, verbal and written, will reflect the PCAST Report's ability to address what I see as the seven principles that generally define what patients seek in an HIT solution. While I will first go through all seven, I'd like to spend some time on three of them, particularly being responsive to the questions that were posed to this panel, and as time permits make some additional comments on patient engagement in this area in general.

The seven principles that generally define what patients seek in an HIT solution or a comprehensive HIT policy are just that: comprehensiveness, accuracy, priority, safety, efficiency, privacy, and quality. So let me go through those in a bit more detail before I come back to comprehensiveness and privacy.

Comprehensiveness: From a patient perspective, an electronic health record should aggregate all information across time, specialties, institutions and practices.

Accuracy: The second principle is one that unfortunately I seldom hear mentioned in these discussions. It often is given sway to privacy and security concerns. But having personally faced situations where I've been attributed with the wrong conditions, conditions I no longer have, medications I'm no longer on, I think some of the questions have been posed today about duplications. The great problems that a lack of accuracy in electronic health records poses both for the potential for clinical error and patient harm, so I would urge certainly more emphasis on better entry of data and more attention paid to better curation of the data.

Priority would be the third principle. The PCAST Report does a good job of giving some examples of how a physician can be alerted by various functionalities within the electronic health record to make the most of their encounter with a patient.

Safety: There's been a discussion certainly of the use of electronic health records for alerting to adverse events. I might also say that greater analysis of this aggregate data using a comprehensive electronic health record system would also allow for better outcomes in some populations that are often under-represented in clinical trials. It's troubling to me that although there was a passing reference to the quality chasm there was not any attention paid really to healthcare disparities.

Efficiency: There was attention to the physician workflow certainly, but patient productivity and the time savings to patients through an EHR system should also be noted.

As to privacy, which is certainly of top attention to this panel, I would like to say that there's a wide range of patient perspectives on privacy. I think we cannot ignore the rise of patient sharing data about themselves on social media when we discuss what patients want and patient preferences in privacy. I think, however, it's important that they be grounded, first and foremost, in patient choice. We shouldn't underestimate the ability of patients to make those choices about how they wish to share their data, nor should we presume that putting a system where patients are in control of their data would interfere with the laudable goal for research and other sharing. A significant amount of plain language explanation of a new privacy schema would need to be made as well as standardization of forms. I've been confronted with a different patient privacy form in every doctor's office. They usually say that they can change the privacy policy at any time, that they own the data, they may not ... restrictions, and that does not engender trust.

Mark Rothstein – University of Louisville – Chair of Law and Medicine
Thank you very much, right on the button. Our second remarks are from Dr. Peel.

Deborah Peel – Patient Privacy Rights – Founder & Chair
Hi. It's wonderful to see so many people I know and to meet people that I haven't. I'm Deborah Peel. I'm a practicing physician still, for over 35 years, in the most sensitive specialty in medicine, mental health. I'm an authority in psychoanalysis, and I'm here representing Patient Privacy Rights. We have 12,000 members and we also lead the bipartisan Coalition for Patient Privacy that has 10.3 million members. We represent the most important issue that is Americans top priority in health systems is the control of their data. It really is very, very simple. People should make the choices, and so we were really, really encouraged by the PCAST emphasis on the need to engineer privacy into the system now.

This is kind of an emperor has no clothes sort of moment, if you implement interoperability in a universal format for data exchange without putting controls in place on where the data goes, the data goes everywhere. It's just pretty obvious; the data will go everywhere and be exposed. And so we really very much welcome PCAST's recognition that it really is time to do privacy simultaneously and up front, build these systems correctly because it can't be grafted on later, and some of you may remember our comments about meaningful use. We've been saying this from the beginning, you have to engineer the controls in up front and we do feel, and just to clarify things, consent is essential but it's certainly not sufficient. We have never been only about consent. But without consent, the systems can't be trusted.

The other things that it's time to look at are the incredible difficulties of deidentification. We appreciate that PCAST wants to find a way to share data that saves privacy, and we would probably not all even be here if there was a way to do that, where data really could be protected from deidentification, so that needs a lot of work. So we're saying that we don't think that the time frames are realistic in order to achieve the goals and we've got to have systems that really will be trusted. I would just say that it's really not just the polling that makes the difference, because the polling is off the charts for people wanting to control their data. AHRQ found that when they did 20 focus groups around the country, people thought controlling their data was a matter of principle, that there wasn't any reason to use one size fits all. That

of course is the beauty of technology, that it can give each of us really the ability to set our own privacy controls, and so that's what we're working for is each person's right to choose and expectation to choose.

So people polling in surveys have been very, very consistent, off the charts, people want to control data, but what I really want to point out to you is these aren't just words that people say, they're actions that people take. Again, I'm going to quote HHS' own studies. We know that from many years ago, and this has not been repeated, over close to 600,000 people a year refused to get early diagnosis and treatment for cancer. Why? Because the information won't be kept private. In my field it's very well known, people will absolutely refuse to get essential medical treatment for depression, post-traumatic stress disorder, when there's no privacy, HHS figures were 2 million a year, and this was years ago. As the public is learning more and more about how insecure these systems are, with the breaches, with the inability to trust, people are going to stop getting treatment, essential treatment, and if they don't come in to see me, the doctor, guess what, guys, there isn't any data. There's no data to share. There's no data for research.

The other thing that's really important to understand is the public has not signed on to a broad research agenda. They haven't done it. In Allan Weston's report for the Institute of Medicine, that was essentially ignored, he found that only 1% of Americans would agree to the unfettered use of their data for research, only 1%, and only 19% would agree to unfettered research use for data with an IRB with deidentified data. Guys, that is not a vote of confidence for this research agenda, and I want you to know as a physician and someone who wants to improve the health of my patients, I want research. The route to research is asking, is getting informed consent, and we have the technical tools to do that. We would urge you to put the cart behind the horse. Thank you.

Mark Rothstein – University of Louisville – Chair of Law and Medicine
Thank you very much, another on the button and interesting presentation. Now, Ms. DuBow.

Joyce DuBow – AARP Public Policy Institute – Associate Director
Good morning. I'm Joyce DuBow from the AARP. We have many millions of people who are members who are age 50 and over, and we have state offices in every state and territory. Just in terms of context, we're pretty active supporters of the quality provisions in the ACA, the HITECH provisions. We think in general that the PCAST Report goes a long way with respect to its vision towards promoting achievement of the triple aim: better health, more affordable care, and better health for people in communities. So I think generally we were quite encouraged by the vision expressed in the PCAST Report.

I would say, because I am surrounded by experts here, that we are not experts and in fact the HIT space is quite challenging for most consumer organizations. We work very closely with people we trust and people we think do understand this space better, like the Markle Connecting for Health, for example. We are indebted to their leadership, the Consumer Partnership for eHealth, the National Partnership for Women & Families, we really do rely on the kinds of support, and there are a few of you at the table, I'm not sure I would do you a great service if I acknowledged your existence, but you know who you are.

At the outset I want to be clear that AARP's position, we want to see privacy concerns addressed comprehensively and effectively with oversight and strong protections, but we also want to see meaningful implementation use of HIT to improve quality and to advance medical science, which includes research. We don't think these two objectives are mutually exclusive. As I said, we were encouraged by the vision for a nationwide capability to secure exchange of health information that would accelerate in our view the triple aim in the PCAST Report. Research as well as our own experience tells us that most consumers believe that quality needs to be improved, that they value HIT and they also want privacy protection. So they want both as well, and we think, as I said, that this is feasible.

We just really feel very strongly that we need to address privacy concerns so that we can remove obstacles towards moving ahead and addressing the obvious quality deficits that we see, the ongoing issues of affordability, we need to do something quickly to address the inefficiency and the quality

problems in the healthcare system. So again, we thought that the PCAST Report presented a compelling vision for moving ahead quickly and accelerating the use of HIT.

I'm just going to highlight a couple of areas in the PCAST Report where we thought more attention could be provided, probably strengthened and improved, with respect to the privacy protections. We think that the report doesn't take into account the limitations of privacy, of consent, and that the additional protections should be supplemented, should be enhanced. We think that the inherent complexities of the processes of tagging privacy data to metadata as proposed in the report is potentially a real challenge for many patients. We think that the role-based ... process also has to be addressed.

So the PCAST Report does give a very clear expression to policy protection, there's no question about that. The concern we have is that there's not enough detail for us to really understand it. It could be a lack of expertise, but I read the privacy chapter carefully and again I don't believe that there's enough information there for me to be able to help our members understand what's really being posed. Many of the words are there in terms of persistent privacy protections, clear rules that are enforced about access, use and disclosure and the opportunity for people to have meaningful choice with respect to how their data are used. But the heavy reliance on consent is a problem and the expansion on issues around limitation on data collection and usage oversight and accountability and enforcement of remedies really needs to be amplified, we think. The whole idea is that tagged data is—

Mark Rothstein – University of Louisville – Chair of Law and Medicine
Thank you very much. We're going to have to stop there, but you'll have ample opportunity. We've got lots of time for discussion and we're all curious to see how you get the rest of your remarks in despite the inconvenience of whatever question is asked. Mr. Tien?

Lee Tien – Electronic Frontier Foundation – Senior Staff Attorney
My name is Lee Tien. I'm a Senior Staff Attorney with the Electronic Frontier Foundation. We're not experts in this area either. I'm not a doctor. I'm not even a health lawyer. But we have been working for the last several years on California's State Privacy and Security Advisory Board process, where we have been very heavily engaged with all sorts of issues around healthcare policy, and especially privacy and security policy, as well as how architecture affects policy.

As my written comments clearly indicate, we're very happy with the general direction of the PCAST Report in terms of its emphasis on privacy and security, as well as its strong endorsement of patient consent and patient consent directives. I think I agree with most of our panelists here about how important privacy and security are, but that consent is necessary but is not sufficient. More specifically, we're happy with the idea of distributed storage of highly granular data elements, but with a strong tie with encryption, both during transmission and at rest. We were particularly intrigued and pleased by the idea of a separation of keys from data to provide for highly auditable access to data, because obviously one of the problems always is if you simply get data and the key then it's very, very difficult to monitor how one subsequently discloses ... and those are critical to maintaining privacy and security. Then finally of course, and this was discussed earlier, we're very happy with the idea that there should not be a national health identifier. That said, we think that the larger value of the report is in its emphasis on vision and architecture, and again, in our work in California we found that many of the questions we wanted to address about policy couldn't really be addressed without understanding how the data was going to be stored and moved.

So that brings me to where we're not particularly happy with the way the PCAST Report framed things, and basically we think that there is a problem when you're trying to design a system dealing with our most sensitive medical information to serve too many different goals. We think that it should be really clear that the primary goal of this system and what we're doing over the next umpteen years is patient care, treatment, and quality, the idea that we're also pursuing this system in order to permit a great deal of, say, innovation in an entrepreneurship. That may be something we want as a byproduct, but I fear that it we

aim for it as a goal on a parity with treatment, that we're going to end up sacrificing the privacy and security and thus the trust of patients that's supposed to be the root of the way the system works.

The technology can add privacy and security at one level, sort of a work factor level, making it harder for people to misuse the information, but it can't by itself change the other factor in a threat model, which is the motivation of the attacker to actually exploit the data. That seems to be, I think, the big challenge here. We already have problems with systems security in every area of software and technology. They are endemic to operating systems, to applications, and we don't have sufficient incentives in the commercial markets for truly secure software and systems. What I fear is that in this context by giving more and more corporations and also government actors strong incentives to get patient data or overall laudable purposes you're just creating more and more incentives that are going to be antithetical to the privacy and security of patient information. The last one I want to make is that we also have to be very aware not only of the reidentification issues that I mentioned, but also how changes in the technology are going to actually affect the legal status in terms of confidentiality of patient data. Thank you.

Mark Rothstein – University of Louisville – Chair of Law and Medicine
Thank you very much. Thank all of the panel members for their written testimony as well as their presentations this morning. In theory, granular patient controls would seem to be the ideal solution to the desire to have maximum patient privacy protected, and yet the testimony of all four of our privacy panel members have expressed some reservations about the PCAST approach, and I'd like to see if we can probe your concerns with some more detail. I want to first start out by asking Ms. DuBow and the other panel members something that was contained in our written comments, and I quote, that "The level of consent required to achieve the granularity and vision by PCAST might overwhelm most patients." I wonder if you could explain that and then I'll ask for comments from the other members of the panel.

Joyce DuBow – AARP Public Policy Institute – Associate Director
... a lot of patients. Aside from the privacy area where we are actively trying to get people to become more engaged in their healthcare, we're asking them to change behaviors, and we're now asking them, this proposal would ask them to pay attention to every single encounter that would be tagged as a data element, and it's a lot of work. I think it's a researchable question. I don't think we know whether patients will actively want to do this someday. The question is whether everybody is going to participate and engage in this level of granularity in order to protect their privacy. I think we need to think about people who have different levels of decision making skills. I think we have to think about busy and harried caregivers. I think we have to think about the invincibles who don't worry about healthcare generally. I think there's a whole range of different skills that need to be taken into account and I think it's one of the things that we need to explore. I think it's an interesting idea, but I don't think we know with certainty if this level of granularity is going to work.

Mark Rothstein – University of Louisville – Chair of Law and Medicine
So if they weren't able to come to grips with their elections of these choices, what do you envision would happen? Would they opt out of the DEAS, as the PCAST recommendations would permit, or would they waive all their privacy controls, or you don't know?

Joyce DuBow – AARP Public Policy Institute – Associate Director
Actually, I don't think they would opt out. I think they would stay in there. The PCAST had a very interesting quote acknowledging the need for face-to-face counseling, but they waved right past that one and just asserted that most people would probably learn from Web-based interfaces what they need to know. I think that one is absolutely unfounded. It certainly doesn't conform to our experience. Some people will. I just think again it's a researchable question. I don't, frankly, believe it. I think most people will just not exercise any of these opportunities. I think they'll just stay in there. Then we'll have a problem.

Mark Rothstein – University of Louisville – Chair of Law and Medicine
Dr. Peel?

Deborah Peel – Patient Privacy Rights – Founder & Chair
Yes, I'd love to respond. First of all, I completely agree with Joyce about the need for research. None of the federal dollars have gone into researching existing privacy and consent and segmentation technologies that are out there today. We absolutely need that. As a practicing doctor, and there aren't very many of you all in the room, I can tell you, and you know this also from the California Healthcare Foundation, people do make extremely granular choices. Think about that one item, people refusing to take tests, a specific test. I can tell you people refuse to take specific medicines. People make very granular choices and of course what we find is the ones that are sensitive about privacy, which is at least 12%, I'm sure many more, these are people that have already been harmed by breaches that compromise their lives outside of the healthcare system.

I think one of the paradoxes of talking with this group is the Policy and Standards Committees have been working really hard to try to figure out how to use information in clinical situations and for public benefit. But one of the things that you seem to not pay attention to which is of great concern is the vast flow of health data out of the healthcare system and/or to users that patients do not want. So that's why we want control back. For example, my state, Texas, sells identifiable and deidentifiable hospital data sets virtually to anyone that says they're a research company. If you look at the list of who they are, they're not research companies. They're insurers and they're data mining companies that are going to sell the data, and they give it away after a few years. This is not acceptable. I think you all have to grapple with the fact that everyone is not using data to improve treatment, which is the point, the reason that people come to see doctors. So yes, people make extremely granular choices, and we would very much welcome the funding of research on existing systems, and there are even better ones out there that we saw at the Consumer Choices Technology hearing last June.

Mark Rothstein – University of Louisville – Chair of Law and Medicine
Ms. Cryer?

Donna Cryer – CryerHealth Patient-Centric Solutions - CEO
First of all, I think there needs to be an essential reconciliation between perceptions and expectations. Most patients, most people believe that they own their data and that it's used for treatment and billing. Everyone in this room knows that that's not the case in actual practice. Part of the barrier to sharing and to advancements in the systems that we've been discussing is because providers believe that they have a proprietary interest and that they own the data and determine the rights on how it's shared and used, often, as my colleague has stated, very, very broadly without any patient input whatsoever.

A second point I would make as to the research that has been done and that hopefully will be done in this area is that there's very little segmentation. I think that's why we find perhaps such a diversity and confusion amongst the different studies, because when you ask what consumers want from HIT, that's much too broad. In my view, a consumer is someone who really hasn't had an interaction yet with the healthcare system, or has very little. A patient might be someone who's had some type of acute illness or hospitalization. Then there are experienced patients like myself who deal and navigate with the healthcare system on a daily, frankly, a moment to moment basis. What we want and need from an HIT solution or what we expect from the healthcare system and also what we might respond back to in a survey, or what we might contribute in these types of settings, are very, very different. That's often not acknowledged in the analyses.

Mark Rothstein – University of Louisville – Chair of Law and Medicine
Mr. Tien?

Lee Tien – Electronic Frontier Foundation – Senior Staff Attorney
Our support for the granularity approach to the data here is largely because we think it's needed for segmentation. Now, if you are able to accomplish segmentation in other ways, that's great too. But what we consistently found in California was that whenever we had debates over privacy, security and consent

we repeatedly were told, oh, we can't do that because the technology isn't available yet for that. I have my doubts that that's actually true, but that was the kind of story that we were given. Therefore when we see the PCAST Report promising that this is going to be a means by which there's going to be segmentation and therefore a patient in consent control of highly sensitive information, we think that's a good thing. The problem, though, or the concern I have, as indicated in my written testimony, is that when a system is designed for multiple goals then we worry that that kind of highly granular data structure is going to promote increased transmission and increased velocity of exchange. If that exchange isn't secure and if we don't have the correct legal and regulatory ... for controlling how it's actually going to be used once it gets somewhere, then we are solving one problem by fueling another.

In the current ... when we look at the pending Supreme Court case of IMS Health and Sorrell, which really exposes what I think of as the soft underbelly of, say, prescription data mining. Just how much money is it chasing, patient data that they already have little control of because government regulations require that it be transmitted in a certain way, thus making it available into the commercial sphere and has a vast industry sitting on top of it. We don't have a clear vision of how well they're actually securing it, how well they're deidentifying it; these are the kinds of incentives at a large systemic level that I worry about when you begin designing a system that sort of puts those goals at the same level as treatment and patient care.

Mark Rothstein – University of Louisville – Chair of Law and Medicine
If I may, I'd like to follow up that point that you made, because it's one that appears across the board in your testimony, of all the panel members, and that is concern with secondary uses. I'd like to ask you to clarify, because it wasn't clear from the testimony, is it your concern that we will not be able to develop sufficiently robust deidentification techniques, or that notwithstanding deidentification, even if it's effective, because there's a lack of patient consent or authorization you're opposed to secondary use of the information without a patient's approval. So let me start, I'll just go down the line, Ms. Cryer.

Donna Cryer – CryerHealth Patient-Centric Solutions - CEO
I have great faith in our nation's ability to provide technological solutions, so if we have not solved deidentification yet, I believe that it can be. I think the essential problem is that this hasn't been staged appropriately for the American public no matter what segment in terms of explaining why we would even want to do these things. So we've gotten ahead of the American people on the issues and unless we spend some time, and resources have been referred to, to really discuss how health information can be used, the potential to promise the benefits to individual patients and the benefits to population health and walk patients through it, we're going to experience a backlash. As you've seen in some of the survey data, where patients just freeze up and just say no. And that's unfortunate, and I think it's a loss to our research and other abilities. But until we take that time it's a very similar situation to clinical trial recruitment. That can be done correctly or incorrectly. If this is done correctly, I think that you will see consumers and patients embrace broader sharing of their information and actively participate in it. But until we've taken the time to include them and integrate them into this process as full partners we will continue to see the backlash against sharing.

Deborah Peel – Patient Privacy Rights – Founder & Chair
You all will be pleased to know that patient privacy rights now does have a technical expert, Professor Andrew Blumberg from the University of Texas, so we're going to be prepared to be able to respond to you in more technical ways if you want to hear from us. Of course, Professor Blumberg helped prepare our remarks. We are convinced that there can be effective deidentification, but we do not have the models yet. There needs to be adversarial testing to make sure that whatever methods are used are effective and actually achieve what they want. I would draw everyone's attention to the wonderful paper that Lee Tien submitted as a resource. It was by the two, again in Texas, UT, rock star computer scientists, the guys that reidentified the Netflix database, and it explains very succinctly why, guys deidentification is incredibly, incredibly difficult because of all the data that's out there. So we really think that some period of study, six months to a year on different techniques with adversarial testing, and really research on these methods to see if they work or not is essential before we can talk about that.

There was a second part to your question, I think.

Mark Rothstein – University of Louisville – Chair of Law and Medicine
The question was, and I'd ask all of you to be brief because we've got lots of questions, and that is, even if we could deidentify the information are you opposed to the use of deidentified information without additional consent of the patient where the information will be used for secondary purposes?

Deborah Peel – Patient Privacy Rights – Founder & Chair
Oh, if we could actually effectively do it, of course that would be a wonderful solution. We have said that there needs to be consent for all secondary uses because we're not convinced that what's going on out there now is effective, so I would urge you all to look at this brief paper that Lee Tien presented. But secondary uses are very, very touchy for patients. Thank you.

Mark Rothstein – University of Louisville – Chair of Law and Medicine
Ms. DuBow?

Joyce DuBow – AARP Public Policy Institute – Associate Director
I would just agree with what Donna said. I think the analogy is in the shared decision making world where we want people to have full knowledge of all the risks and all of the benefits. They don't have that right now. That's what we need to do. So I think that when we have full disclosure and full transparency we'll have a better opportunity to understand this issue better and know where patients are with respect to the secondary uses.

Mark Rothstein – University of Louisville – Chair of Law and Medicine
Thank you.

Lee Tien – Electronic Frontier Foundation – Senior Staff Attorney
Again, our concern with respect to the deidentification and reidentification is that the threat, from all we can tell, is a very serious one. And because it's a function of all information that's available about individuals that is capable of distinguishing them from one another, you can never properly evaluate or assess probabilities of reidentification simply by staring at the data that you are about to release. It is always a function of all of the other data. And because in our modern environment there is an enormous amount of information about people shared that ties to location and various other things that are extremely usable for reidentification it's therefore really difficult to get a good handle on how well you deidentified something. So I think of this as a cautionary principle of saying that we should be extremely wary about how we handle information when we cannot be sure about whether it is truly or for the foreseeable future deidentified. Because all of the trajectories that contribute to reidentification appear to be moving in the wrong direction, excess computing power relative to population size, amount of revealing information, etc.

The other point—

Mark Rothstein – University of Louisville – Chair of Law and Medicine
I'm sorry. We've got a whole line of questions. As we did with the prior panel, we'll give the first crack to the members of the working group and then broaden it. I also want to alert that the folks online who are working group members; we're going to give you some time at 11:15 if you have questions. Dr. Stead?

William Stead – Vanderbilt – Chief Strategy and Information Officer
Is anyone on the panel aware of people that have developed a framework for identifying questions you can ask at the time the data is captured about what you think of that data being? For example, whether you think of it as clinical or whether you think of it as demographic, that could then be matched up to your current opinion at the time the data's going to be used about whether you want it used in a particular way. I'm trying to get at the difference between what I would think of as things that we would need to bind to

the data early, and things that we would then be able to bind later at the time of use? Has anybody done work in that space?

Deborah Peel – Patient Privacy Rights – Founder & Chair
I don't know of work exactly in that space. But again I do know, from some of the presentations at the Consumer Choices Technology hearing, there are some systems that come close to identifying patient preferences in a particular time. We're concerned that the system for consent needs to be done in such a way that it can be changed dynamically. So that doesn't mean that meta tagging shouldn't happen, in fact, meta tagging is a good framework, it depends on how it's used. But people should be able to change their consents dynamically in one place through some kind of a consent tool or a consent system, and we think there ought to be research about that and that the consent tools themselves can include educational material and drop-downs about the risks and benefits of making certain choices. But we would really welcome research about exactly what you're saying.

Lee Tien – Electronic Frontier Foundation – Senior Staff Attorney
Can I jump in here? One of the very, very clear empirical findings in terms of consumers, general consumers' expectations of privacy, is that there's an enormous disparity between what consumers expect and what they actually get. In the normal consumer realm time after time, study after study shows that consumers believe things like if a Web site has a privacy policy therefore their privacy is protected. They have very little understanding that these privacy policies are actually legal documents designed to protect a Web site in how it uses their information. One could go through lots of evidence like that, but the point is that consumers' current expectations don't match reality and consumers' preferences are not informed by any real significant understanding of how their information is being treated.

At CalPSAB, we did a chart on the flow of ePrescribing information which, as you can imagine, was fairly complicated. Whenever I do a talk to a general audience on health record privacy one of the first things I do is I show them that chart and I say, does anybody in here have any idea that your prescription data goes around the economy this way? Of course no one does and they're all appalled. So the simple point is that, relative to your question is that I don't think we know how to project and I think peoples' preferences, and I think what's very clear is peoples' current preferences are not informed by the true nature of the market in health information.

Joyce DuBow – AARP Public Policy Institute – Associate Director
Can I just make one observation, that it seems to me that it's an enormous burden to be asking patients to be making those decisions in the moment. There are so many other things that are being taken into account during an encounter that, to Deborah's point about the need to have the opportunity to change these preferences, I think is really very important. But during a moment for many patients, again, I'm focusing on our population, which is 50 and over, they're the people who use the healthcare system the most, and it's just one other piece of a very complex situation.

Mark Rothstein – University of Louisville – Chair of Law and Medicine
Dr. Halamka?

John Halamka – Harvard Medical School – Chief Information Officer
... the wisdom of the panel, so as an emergency physician I think data exchange for care coordination is important. It improves quality, efficiency, and safety. As a CIO of course I want to make sure patients have opt-in consent and control of the flow of that data. But a very fine adviser, Dixie Baker, once told me that the more complex the system, actually the less secure it may be. So in Massachusetts when we decided care coordination was important but patient consent was important, we said probably given the state of technology opt-in consent at an institution level is about the best we can do. It's very challenging for me to take a highly unstructured electronic record, and sure there's some structured data but there's a lot of free text, and say oh, based on your preference for not disclosing mental health, HIV, STD, etc., I will ensure that there is no sentence in any note that implies any of those conditions.

But if you say I have a real discomfort about sharing this whole institution's record about me, that's pretty easy for me to just turn off. So in the interest of the PCAST Report, which wants us to move forward in an evolutionary manner from what we have today, how do you feel about this decision that I've had to make, opt-in consent at an institutional basis as a way of starting us until segmentation and granularity is better?

Donna Cryer – CryerHealth Patient-Centric Solutions - CEO
Right now, the reality is that a patient comes into a doctor's office or an ER and they're given a sheet of paper and just told to sign. It's supposedly the privacy policy. They don't read it. They don't understand it. They sign away. It's whatever the underlying privacy policy, which wasn't included with the form in the first place, happens to be that institution. So any step forward would be an improvement over that, so that's my first statement.

The second is I think that a multi-step, multi-platform way of structuring information, and it doesn't have to be an extensive so that each meta tagged piece of data has a different consent, I think there can be some large buckets, as you described, it gives patients opportunities to explain their preferences of sharing that data. To Deborah's point, we don't ask people to come in and draft their advanced directive on the spot. We give them time beforehand to consider these. So whether it's Web-based education, as was included in the PCAST Report, face-to-face education, there needs to be a multi-step and because this is a cross-generational solution, a multi-platform education process to get patients to make some initial distinctions and ... choices about their privacy setting. Then be able to change them or adjust them over time and over situations, I think is the direction we need to go in.

Deborah Peel – Patient Privacy Rights – Founder & Chair
John, I'm sorry but the need to segment has been built into state laws for a very long time, several federal laws, and we also need the right to segment information in order to just send the minimum necessary forward. We need to be able to segment and not send records when patients pay cash so that they're insurer and health plan doesn't get the data. It really is time to do segmentation and we understand this isn't what the panels want to hear or what HHS wants to hear, but we can't do this right unless we slow this down and build the privacy protections in now, including in particular segmentation.

I'll just tell you one story of a complaint we got from a VA doctor, where as you know everything is in the record, the record goes to everyone who sees it, and so mental health records are part of them. So he told a story about a patient who came in to get a shoulder x-ray and the technician said, so, are you still suicidal? There's a real need, even within an institution, for privacy because I guarantee you many people don't want someone who has no need to know knowing things about them that might disturb them or might affect how they treat patients. My patients are very, very sensitive about other physicians and other people knowing that they see a shrink because we actually have decades of research that show if you have a diagnosis you get worse medical care, actually you get worse care. So the need for segmentation within an institution is very important too.

Joyce DuBow – AARP Public Policy Institute – Associate Director
I don't know that I understand all the implications, but I think we already do segment information. I don't understand very much how that's different from what we already do essentially.

John Halamka – Harvard Medical School – Chief Information Officer
A quick comment on that is that I could segment a structured piece of data like a medication list, in fact, in Massachusetts by state law we actually have what's called a restricted drug list, HIV, mental health, substance abuse drugs, and I could filter that. I can probably do the same for structured problem list. If the doctor writes a note that the patient was feeling sad, that's a little bit challenging for me to, in an automated fashion, redact. So this is the challenge, is that the medical records data is a combination of things that are easy to segment and things that are hard. So that's why at the beginning I just said institutional consent to disclose is a place to start.

Mark Rothstein – University of Louisville – Chair of Law and Medicine

Mr. Tien?

Lee Tien – Electronic Frontier Foundation – Senior Staff Attorney
My perspective on this is pretty basic. I agree that complexity can confound a lot of the best intentioned systems and we have to be really vigilant that it doesn't actually push us in the wrong direction in terms of what we want to do. That said, I think that the goal of segmentation is so clearly imbricated in what we want to do with patient data and what patients want to do with their data that it can't be ignored. So the answer, to the extent that there is a tension here I think that means you go slow, you do it very, very iteratively, you make sure that you're not creating and that you ward off the incentives and running the security in the system in order to basically watch out for cutting corners.

Unfortunately, these are already existing incentives for cutting corners even in both our paper and electronic systems. So this is a ... area that requires cost vigilance, which also means—and this is the other aspect of my testimony, the need for very, very clear auditing and enforcement and regulatory stuff on the human. The technology cannot address everything and you have to match all of this with an actual compliance effort, which historically has not really existed. We don't have really a good handle of how as we accelerate the flow of data and increase the volume, how well the current equilibrium of compliance is actually going to stand up. I think, again, this is why we recommend really, really staged development, really, really careful pilot projects, serious adversarial testing, strong assumptions about actors in the system not being trustworthy, these are the only ways that you can actually really build a system that you think is going to last.

Mark Rothstein – University of Louisville – Chair of Law and Medicine
I think we have, from my quick count at the moment, six working group members with questions. I would suggest if possible, if you could address your question to one particular panel member that might speed things along. I would ask the panel members to try to be brief, if possible, in their responses. We want to get all the questions answered. Mr. Stack?

Steven Stack – St. Joseph Hospital East – Chair, ER Dept
I'm an emergency physician. I thank you for your attention to this. Privacy is absolutely imperative that we get it right. I do think we're asking a lot of patients to do this. I'm only relieved to know that we asked so much less of the physicians in this environment right now. I think the complexity of consent cannot possibly be overstated. The numbers of ways data and information is used, that patients would want it to be used, quality review, review of a follow up question they have, the number of people who touch their data in service to them, I think is enormously complex and is never going to be fully understood. That doesn't mean I don't advocate for transparency, but that's very complex. I think we have spectrum bias. I think that a small number of consumers are really legitimately and sincerely concerned about what happens with their data. The vast, vast majority are far more concerned about not getting killed, crippled, maimed, harmed and the frustration of don't you people talk to each other when you care for me. I think they want their data to be used for their well-being and right now, we have a system that doesn't afford this.

This is building up to a specific question for Dr. Peel and Ms. DuBow. I think patients avoid treatment and disclosure because of the stigma attached to diagnoses, future prejudices in their care, if they're celebrities, for understandable reasons. But I think far more than that smaller subset are people who avoid disclosure because of the economic implications to them, recision, exclusion from coverage, what an employer may or may not do to employ them if they have a prospective employer, future things. It has nothing to do with the actual provision of clinical care to them. So I think we're blurring some issues and I think we need to be very clear about that.

The question is this, if Dr. Peel and Ms. DuBow can expound a little bit more on this concept of granularity, because I don't believe the technology is the barrier. I think there are smart people around this table who can program systems to do this stuff. My concern is, so using HIV, if you block HIV then do you block every medicine that they're on, because potentially those give secondary clues. Do you block

their allergy list if they're allergic to medicines that could be treated for HIV? Do you block their diagnoses that are only due to HIV, so Pneumocystis carinii pneumonia, which really only an immunocompromised person would get? Where do you stop blocking and how do you do that. To John Halamka's comment, the more and more you block the less and less it's helpful. You may help the 1% who have a very sincere concern, but you sure are going to hurt the 99% who really need that data to be available to physicians providing care. So if you can expound on that, because I think it's a really daunting problem.

Deborah Peel – Patient Privacy Rights – Founder & Chair

What I would say is, first of all, the reason I started Patient Privacy Rights and the whole reason for the need to control who sees data is really jobs and credit. People also feel very intruded upon and harmed and it's a matter of personal identity as well, not wanting people to know the most intimate things about you. In terms of granularity, in the example you're giving this is where doctors have to talk to patients, who is it that you don't want to see information about this and why. Because there may be very valid reasons for going all the way down to the granular level of every diagnosis, every medicine, everything that's part of the record that refers in some way to HIV and there may not be. So, first of all, you have to really understand what the concerns and the problems are. I think when patients know that someone is really acting in their best interest they will tell them things. I don't know about you but I've worked a long time in emergency rooms too and when people trust you and think that you're not going to share sensitive information with people that shouldn't have it, they're very willing to speak.

We all cope as physicians with missing information. Electronic health records aren't going to fill the gaps because we're still going to have missing information because people won't participate because they think the information's going to be disclosed, so we have to deal with gaps in information too. But we need to test these kinds of systems for consent and granularity, whether the data is able to be segmented within a document and starting with document level segmentation or whatever, but people really do, and I think you know this too, most doctors don't actually want to know everything about you. They really want to know the things that are relevant to providing the kind of help with a problem that you have, not the entire universe of data. So the point is who has appropriate data to make the best clinical decisions, and appropriate data isn't all data, and so that's another reason segmentation is important. Also to be able to segment erroneous diagnoses that people get, we need to be able to prevent the flow of the wrong diagnosis going out there too.

Joyce DuBow – AARP Public Policy Institute – Associate Director

I agree, I think with the general drift of your point. I think what we have failed to do is to help people understand the value of sharing data. We've also failed to give them confidence in a trust framework, and I think those are absolutely essential ingredients to move forward. I can't tell you specifically where I think the granularity should stop, but my guess is that there probably are reasonable places where you don't want that to happen. But more importantly, we need to help people understand the value of the information sharing and what it does in terms of their own treatment, what it does with respect to research as a social good, to inform our understanding of treatment, etc. So I think that we just have a lot of work to do. The business about going slow troubles me. I honestly say I'm not a techie, but I have enormous confidence in those of you who are and I think you can figure it out. I think we have to move ahead with urgency. These are very, very important areas and we need to do it quickly. That's not to say that it shouldn't be a thorough understanding of what we're proposing, but we should get on the stick and do it.

Paul Egerman – Software Entrepreneur

Thank all of you; great discussions, very interesting. These issues of granular privacy are complicated, and Dr. Peel and Lee Tien you're advocating some additional research before we launch anything. One of the things I think is very interesting in the PCAST Report is its references and discussion about the PHR, the personal health record, which, as I read it, I was thinking of it in terms of what some people call an ... PHR, something that is separate from the record that the provider keeps. I'm wondering—and I'll ask this question of you, Dr. Peel—as you advocate for additional research, if it's possible at the interim step that the PHR might be helpful, at least for some patients, that that might be a vehicle for patients to,

in effect, make granular decisions about how they want their record to look. Really separated from their involvement from their provider but submit that to providers, and healthcare providers would understand they're getting the patient document as opposed to a document from one of their colleagues. But what would you think about that as at least an interim step to try to make some progress towards some granular options for some patients?

Deborah Peel – Patient Privacy Rights – Founder & Chair
Yes, we think it would be a good step. You and others here might know that in some places in Europe the PHR is the method for data exchange. Data is only exchanged when the patient gives it from one provider to another and that's the main way that the data works. That could work. It could be a helpful step for segmentation. As a physician, the person I trust most is the patient, their information, their history, the whole nine yards. You're going to make a more accurate diagnosis if you listen carefully and understand your patient than if you read five reams of records. It's not that records aren't important, but the person that has the greatest interest in the accuracy of the record and the completeness of the record is the patient, yes.

Paul Egerman – Software Entrepreneur
It's interesting, so it's one of these things like be careful what you wish for. We have this entire system in place and we really have access to all of the data. It might be confusing because it might be a lot of duplication and the patient's record actually might be the clearest, because they would clean it all up. So it's very interesting.

Donna Cryer – CryerHealth Patient-Centric Solutions - CEO
I would like to make a point that I'm not a fan of the untethered PHR. I think that there's a false dichotomy between a patient health record and an electronic medical record, or at least there should be. Patients, for the most part, want a portal into their medical records. I'm one person. I need one record that holistically describes all of my ... interactions and conditions. So having a PHR as sort of a disconnected or piecemeal offshoot I think is really unsatisfying. There does need to be a specific patient interface, a method of entering and validating patient generated data, which as Dr. Peel pointed out, can be so valuable for making and guiding clinical decisions, as well as tools for appointment scheduling and other convenient functionality that should be well integrated in EHR. So I get disturbed and uncomfortable with an uncoupling from a patient version and the real official medical record.

Mark Rothstein – University of Louisville – Chair of Law and Medicine
Wes?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Thanks. I had an opportunity to learn something here. I know of a number of countries in Europe where there are proposals on the table and projects underway to use the personal health record as a means of controlling communications among physicians, and of course, they're getting care, I just didn't know that any of them were implemented. Could you tell me which countries those were?

Deborah Peel – Patient Privacy Rights – Founder & Chair
I think there's a Tolban project that was talked about during the Consumers Choice Technology hearing last June. I think Tolban has some. There are other systems in Europe that are in between a PHR and an EHR. My understanding is in Germany that the only way to get access to the record is if the patient's card goes into the machine and the doctor's card simultaneously and then the doctor can see your data. But there are many systems in Europe where the patient is the controller. Maybe some of them are PHR or maybe some of them are EHR systems, but we could learn a lot by looking at their also their frameworks beyond consent.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst

I agree that there are things to learn there. I just wanted to make sure that as we look for that information we look for what's proposed, what's implemented in a pilot community and what's implemented on a national basis, because often the issues that are of concern to us are issues of scalability.

Mark Rothstein – University of Louisville – Chair of Law and Medicine
Art?

Art Glasgow – Ingenix – Chief Technology Officer
Concerning some of the questions that you've been discussing, there were a couple of questions that when I read the PCAST Report I thought of. One of them was, can patients decide the metadata tags? So that was one we've discussed. Then opposite extreme, I had the thought, how much do we actually scientifically know about our ability to do data segmentation? These two questions lie at an opposite extreme. On the one hand, how much can we expect patients to know about how to do this? Then, forgetting all that, how much does the best expert know about how to do it? But I got a little bit of help. There was this, I think Dr. Peel mentioned this, the Consumer Tech Choices conference, and there were a number of presentations of people who think they have ideas on how to do some of these things. So it made me think that there may be some merit to the idea of putting patients in control and creating an entrepreneurial environment so that maybe something like your organizations might be able to help people with these processes if they can make their data available. For example, in some of the Consumer Tech Choices conferences, there would be vendors who proposed ways of helping people decide how to expose their data, and I don't know how good an idea that is. I thought I'd ask you.

Deborah Peel – Patient Privacy Rights – Founder & Chair
Let's see, I'm not sure exactly what to respond to. There's a tremendous need to study what people are willing to share their data with and for. But I guarantee you people really are altruistic and do want to share data for research, it's just that I don't think most Americans would be happy knowing that Thomson Reuters sells longitudinal patient data to various customers, and they're out there advocating that all HIEs be designed opt-out, so everyone's data goes in and they benefit. If people want to participate in some type of application of their data, they should have the right to do that if they have the information and understand all the downsides of it, yes.

Art Glasgow – Ingenix – Chief Technology Officer
Part of the problem we're dealing with is deferred maintenance in terms of patient and consumer education about the healthcare system. We've experienced amazing changes over the last 25 years and a system that might have felt relatively stable back then has changed dramatically, and patients haven't really caught up with that. But in some ways that strikes me as a transitional problem that we can address, and part of what I think you're sort of pointing to is patient consent decision support tools. If we have clinical decision support tools, why can't we have patient decision support tools and we can try to take advantage of increased transparency in information flows.

I can't imagine if the government is putting resources into this that they can help innovators and entrepreneurs by subsidizing some of this work, and how can we use those very same tools to make sure that every AARP member or patient has a much better understanding of and has the best tools for figuring out what they should do. Because obviously right now one of the concerns that providers, and especially small providers have, is that they're going to have to undertake all these burdens of trying to inform patients of what's going on. They don't have confidence that they understand everything that might be happening with their data, and there's just a whole lot of uncertainty in that area. But I think it's a problem that's not going to go away and so it's something that has to be directly confronted as a problem to be solved and resources devoted to it.

Mark Rothstein – University of Louisville – Chair of Law and Medicine
Dixie?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences

I want to start by complimenting Mr. Tien for pointing out in your testimony the importance of defense and depth and dependencies within systems. I agree with you that they're too often overlooked and we look just for an application to do all the work, and also for providing the ACM paper. For those of you who haven't read it, that's one of the best papers that's ever been written on the complexities of deidentification.

I know that everybody on this panel realizes that privacy is context specific, and we talk a lot about context specific with respect to health information, but privacy is certainly context specific. And if we look out at social networks, and people don't seem to care about it at all, and we look at the way people sign their HIPAA notice of privacy practices and don't pay attention to it, that doesn't seem to bother them. But it also changes over time. I know one of the examples that we talked about in an earlier meeting was HIV testing, where the fact that you had an HIV test ten years ago was very, very sensitive and today some employers require that you have an HIV test. It's not all that sensitive at all. The PCAST Report seems to imply that the way to go is static binding of privacy practices with data.

So my question is, and some of the questions and discussion have skirted on this point but I want to really focus on it, at what point and how would you propose to bind privacy preferences as metadata to data? For example, Bill Stead asked a similar question, at what point should you really bind, but I would like to extend that, should it be bound permanently over time to the data, or should it perhaps be bound at the time used, at the time it's exchanged? I'd be interested in hearing whether you think it should be statically bound, dynamically bound, or some combination. I would also add that I'd like you to assume that we have decision support tools to help consumers make these choices.

Joyce DuBow – AARP Public Policy Institute – Associate Director

I think that it cannot be statically and irrevocably bound, that does not reflect the preference of any segment of consumers or patients. As you pointed out, people change over time, their circumstances change, their understanding of their healthcare system, their life circumstances change, the different types of data that may be added to their medical records change over time, and so their preferences must be changed. I think that just as you're asked to sign that completely irrelevant form every time you go into the doctor's office, or at least annually, I think that's certainly no less than annually or with no greater burden would your overall list of preferences. Maybe not at the exact level of the metadata tagging, but in certain segments and categories of it as you walk through a decision tree, could easily be changed either on an annual basis or with each encounter with that particular facility's office.

... situations change. You can envision a caregiver who's an authorized representative for a patient, for example, needing to have the opportunity to change preferences that were designated at an earlier time for convenience, for example, to gain access and to allow data sharing. It is situational. There's absolutely no question about it. I think preferences change when you age. We know people with multiple chronic conditions are probably more willing to share information than those people who don't have those conditions, so there needs to be built into a system to allow peoples' preferences to be acknowledged and to be honored by allowing them to change those preferences.

Lee Tien – Electronic Frontier Foundation – Senior Staff Attorney

I'm not sure I fully understand the question, because I think, point one, I think it would probably be a good thing if the tags were immutable, because I worry very much about the wrong actors messing with the tags. On the other hand, I don't see any reason why, say, having one immutable tag means that you can't also add a layer to an immutable tag. So I guess it's more my idea in terms of how the architecture will work and how the data will be tagged is that it will be multiple tags on it. To the extent that a person at time A had a particular privacy preference that was pulled in from their consent directive, and say they updated their consent directive or the consent directive structure in fact changed because we added new categories. In other words, new fields or something, that those could be updated in the tagging associated with the relevant data on this. It would not erase the prior tag, but it would add on to it, sort of as a ... system so you would have a history of the privacy preferences associated with the elements. I thought that that was within the parameters of the PCAST model, although it was probably sufficiently

under-specified that you can't be sure. But that's the way that I conceived of addressing the problem when people asked about static versus dynamic binding. It seems like you can add tags.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
But you are saying that you concur that the tags would be persistent with the data over time?

Lee Tien – Electronic Frontier Foundation – Senior Staff Attorney
Yes, we think it should be persistent with the data, because I believe, one, the threat model here is that the data, it loses the tag that reflects the patient's true preference. The bottom line is we want to make sure that the patient's true preferences with respect to the data are being respected and that it's not running with the tags. Then you have to assure me that the rest of the architecture is going to make sure that it's there, because there are a lot of out of band ways to deal with data. You can't close them all off, but I think that within the system you want to make sure that it is not easy to remove the tag.

Mark Rothstein – University of Louisville – Chair of Law and Medicine
We're going to have to get another question now. Thank you. Stan?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
I appreciate the advocacy for privacy. I'm sitting here thinking in my role as a CMIO at a not-for-profit healthcare provider another aspect of this seems to be, or a potential conflicting set of circumstances is the business needs of care providers. As care providers, our goal as a not-for-profit is to provide the highest quality care at the lowest appropriate price, take the best care of patients that we possibly can. In doing that there are a bunch of things that we want to do internally in terms of quality assurance, monitoring costs, reporting and tracking potentially internal epidemics, supporting device recalls and notifying patients if their devices are found to be defective, etc. So there seemed to me to be a bunch of what I would think of as legitimate business needs for use of the data that are actually in the best interest of the patient but do also correspond to, if you will, the needs to run and support and have a viable business model. Do you see a conflict between those needs and privacy? Would you have any guidelines about how we can adjudicate, say, the legitimate needs to run a business versus privacy issues?

Donna Cryer – CryerHealth Patient-Centric Solutions - CEO
I don't really see it so much as a privacy discussion. I think you perhaps misconstrued some, at least my comments if you think this is merely a privacy panel, but it's a patient panel. I think I would distinguish your comments as a difference between true clinical ... that benefit the patients, and your business needs. I would say respectfully that your business needs need to be subsumed to my needs as a patient and to those clinical needs. We have to decide if we're going to have a patient driven system or a provider driven system and some of those questions will answer themselves once we choose a different paradigm under that which we've been running healthcare to date. I, for one, as one of the complex patients that Joyce referred to, you can put my healthcare information on a wall in Times Square if somebody will use it to improve my treatment. But there's a spectrum of patient preferences that needs to be respected. And it's that patient preference, it's that elevated patient role that I think is really what at least I would want the panel to take away from my comments today.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
I don't think I expressed myself well, because I couldn't agree more with what you said, but it is that patient focus actually that I'm talking about. The fact that by quality assurance I can detect that I have bad physicians practicing and I can take action against those physicians so they don't provide bad care to you and the fact that I know there's a care provider who's a MRSA carrier and we don't want them to come into contact with patients. It's all about providing that high quality patient care that drives this, but I wonder if there's any conflicts between that kind of need that is helping, if you will, the population, and ensures the best care to the population as opposed to the privacy concerns of an individual.

Deborah Peel – Patient Privacy Rights – Founder & Chair

I'd like to address that. I think that part of what you're getting at is what is business operations versus what is research and quality, and evaluating quality falls into both. People expect an institution to deliver high quality care, but patients also view quality research as a kind of research, something that they want to know about and be informed of. Frankly, it could be a good way to engage patients in participation by saying, look, we want to make sure that everyone gets a certain kind of stent in our hospital, we're doing quality research on this, we want you to know that we're doing that, would you like to participate? We think it will benefit you and everyone else. I would think that if you use the test of would someone want to know about this and would they want to be asked, and that's the way it should go. Because I think there are tremendous research uses that people are trying to parse out and say we don't have to get a consent for because it's quality improvement or it's pay for performance, or it's comparative effectiveness data or whatever, but we actually disagree with that. The public really doesn't understand all these different kinds of research, population, health, public health, and they want to know, and when they're asked and informed a high majority say yes. So we can get the research we want and engender trust in a non-profit institution or a hospital or a clinic.

Joyce DuBow – AARP Public Policy Institute – Associate Director
If I understand, all of the areas that you described, it seems to me that that's part of your business as a high quality provider. I don't consider it research for you to be performing at a high level of excellence. That's what a patient expects. So all of the areas that you talked about in terms of understanding the performance of the participating clinicians in your institution are all part and parcel of doing business with respect to providing good, optimal quality; I don't see privacy intervening there at all. Those are not research questions that you pose, in my view.

Lee Tien – Electronic Frontier Foundation – Senior Staff Attorney
I see your question as sort of being how do you characterize that quality of care issue. To use the FIP (Fair Information Practices) type model which thinks of primary uses and then secondary uses, where the primary use is nominally treatment of the patient or patient care and then you have this ambiguity about whether this ... larger collective quality of care versus quality of individual care. I would think of that along the lines as a pretty highly tutelaged secondary use. It's not the primary use, but it's right up there. So the question is, well, how do you deal with that, because really normally you're not supposed to use data for a purpose other than what it was originally gathered for.

We have similar kinds of problems in a lot of areas, like in a telecommunications system. Obviously it's not as sensitive, but it's still the content of peoples' private conversations, and so for instance under the Wire Tap Act there is such a thing called a provider exception and so what it does is it treats differently the rights of the provider protect ... to protect against phone fraud and so forth and so on. So it gives them some license to conduct wire tappings or so on for different kinds of quality control. So one can imagine a regulatory framework that addresses certain kinds of things categorically as having some kind of ..., and making an allowance for it, but that doesn't mean that there's no privacy interest in there, because I think fundamentally, there is. It also means that you are putting a lot of burden and weight on compliance and monitoring and oversight, because any exception is an exception and therefore it needs to be ... and therefore you have to actually pay attention to it. Otherwise, it's just a loophole.

Mark Rothstein – University of Louisville – Chair of Law and Medicine
Thank you very much. I want to apologize to our committee members who I'm sure have brilliant questions that they won't be able to ask during this session, perhaps afterwards or some other opportunity, as well as anyone who's on the telephone who might have had a question we'll try to get to those at some point. I also want to thank once again our panel members for their excellent written presentations, their oral testimony, and trying to answer some very difficult questions. My colleagues and I will try to answer some of those difficult questions tomorrow when we take these issues up again. Thank you all.

Donna Cryer – CryerHealth Patient-Centric Solutions - CEO
If there are additional questions, I think all of us would be willing to follow up with them.

Paul Egerman – Software Entrepreneur
What we'll do with the additional questions, if people would like if they could send them to Judy, with copies to Bill and me, send an e-mail. Then we'll get them to the panelists and try to distribute a list of answers, perhaps put them up on our blog or something so that it's also done in the public, but we appreciate your willingness to continue to help us with our efforts. So thank you very much, a great presentation. We could probably go several more days with questions on many of these issues, so thank you very much, and thank you, Mark, for moderating it.

Our next panel is on Population Health, so it's a great segue since there were a lot of comments about that during the privacy panel, and Bill Stead will be the moderator.

William Stead – Vanderbilt – Chief Strategy and Information Officer
Thank you. As Paul says, that's a great bridge into at least aspects of this panel. I'm pleased that Richard Platt, who's Chair of the Department of Population Medicine at Harvard Medical School, and Joyce Niland, who is the Associate Director of City of Hope's Comprehensive Cancer Center are joining us for this panel. Joyce is joining by phone. Are you on, Joyce?

Joyce Niland – City of Hope – Associate Director & Chair, Information Sciences
Yes, I am. Can you hear me okay?

William Stead – Vanderbilt – Chief Strategy and Information Officer
Yes, we can. Thank you. Richard, do you want to take it away?

Richard Platt – Harvard Medical School – Professor & Chair
Sure. Thank you. The conversation we've had up until now I think tees up some of the very important issues that we need to discuss. But just to articulate them one more time, I think that the PCAST Report appropriately identifies the potential to have increased amounts of electronic health information play an important role in improving our understanding of the safety of drugs and vaccines, the benefits of medical therapies. Help us with a variety of kinds of public health surveillance, and to help us understand and improve the quality of delivery of care. The need for population approaches, which is what's needed to address these questions, is fundamentally different than the needs that apply to delivery of care to individuals. Let me name some of the ways in which they're different. It is often necessary to know how many people are eligible to receive a certain kind of care, how many people actually received a specific kind of treatment. How many of them had some outcome of interest, and whether the risk of having one of those outcomes is different because of the treatment that was provided after you take into account all of the other factors that might have influenced outcome of care. So it's important to do risk adjusted differences.

I included in my written remarks an example of a kind of study that my colleagues and I are about to embark on, on behalf of the Food and Drug Administration, to understand whether there is an unusual risk of myocardial infarction, heart attack, associated with certain drugs used to treat diabetes. There are a variety of reasons that FDA chose that, but I'll remind the committee and the audience that last summer there was an advisory committee meeting that determined that a drug that had been widely used to treat diabetes probably increased the risk of heart attack. So that's one of many reasons that the agency is interested in it. That example that I used, I picked it in part because it has a certain representative quality, in part because the protocol's readily available on the Internet, but it is by no means the most complex kind of study one might undertake. Last year we conducted a study for the Department of Health and Human Services to evaluate the safety of the H1N1 influenza vaccine that required assembling information that arose from the care of over 30 million people.

Now, I think that the concerns that I have about the PCAST Report are that it has at least five kinds of threats that will make it difficult or impossible to perform these kinds of studies. The first is the logistical complexity of dealing with the data that would arise in the hands of evaluators. The second are threats to

privacy, which we've already discussed. The third are threats to the validity that would come from non-representative loss of information from certain kinds of individuals. The fourth is a risk of misrepresentation of the data. Marc Overhage talked about the need for in-depth knowledge of the source system. I think we could go several levels deeper in that kind of concern. The fifth is the reluctance of organizations whose care would be understandable to provide the data.

I think we can circumvent most of those problems by adopting a strategy of distributed analysis. Not simply a system of distributed storage of data, but distributed analysis, in which one uses a common data model, transforms the data into the common data model, has the existing data holders maintain possession of the data. Then analyze the data using programs that are distributed to check the quality of the data and then to extract information that's actually of interest; this many people were exposed, this many people have the outcome, the risk adjusted difference was this. They provide that kind of information to a central evaluation team that can integrate that data for an overall summary understanding of the outcome of the population. But the general approach is one that has proven to be reasonably flexible and able to handle a substantial number of the problems that are of interest to our society. Carol was right, it's an immature science and there's a lot left to be developed to make this as useful as possible, but I think it's a compelling alternative to the one described in the PCAST Report.

William Stead – Vanderbilt – Chief Strategy and Information Officer
Thank you, right on time. Joyce, I know you can't see it because of the telephone but we're living by a strict five minute clock.

Joyce Niland – City of Hope – Associate Director & Chair, Information Sciences
Okay, I've heard the consequences if I don't stick to that, so I will try. I really agree with all of Richard's excellent remarks and I appreciate this opportunity to comment on the PCAST Report to the president. The achievement of the universal EHR will confirm any benefits, both to personalized healthcare and to facilitating population based research and helping develop the future most efficacious treatments and preventions. I think that the PCAST Report does a really good job of framing the background and complexity of introducing innovative technology into the healthcare arena and presents a viable path forward for this elusive goal. However, the full solution is highly complex and difficult, as recognized by the working group and the expert testimony being given.

I was asked to comment particularly with respect to the impact on research. As a little background, I am Associate Director of the City of Hope and Chair of Information Sciences. I'm also a principal investigator for three national data coordinated centers, for which I've led the development of Web-based centralized data systems stemming back now almost 15 years. My testimony relates both to the overall premise and the focus on the chapter on health data and research opportunity. The bottom line of this chapter is its importance as the national health IT infrastructure will enable new kinds of research, and I agree with this.

But I don't believe the solutions proposed will be able to fully support this type of advancing by medical research. The key reason is the need to more fully support semantic interoperability. The technical approach of metadata tagged data elements is very sound and appropriate to exchange information, but focusing on the data exchange ... only one piece of a complex puzzle. The approach doesn't fully address semantic interoperability, which is key to a common understanding and ... interpretation for research. It's critical for reuse of the data for population outcomes and comparative effectiveness research, as well as facilitating the conduct of clinical trials. Without the standardized coded data, EHR permission will not be fully useful for research, and because of this gap I don't think it's possible to achieve the stated goals for PCAST within the 2013 timeframe.

Technology components often point to other industries like marketing and retail and airlines, but healthcare information is so much more complex, and so it remains extremely difficult to capture the essence of the human condition, the treatments and the outcomes in a standardized way. Yet we need this fully coded data, everything from presenting characteristics to comorbidities to treatment outcomes and quality of life and cognitive effects as well. So the PCAST Report doesn't address the issue of

common vocabularies for coded data elements. We'll look for combining data elements into meaningful expressions, vocabulary standards such as LOINC and SNOMED CT, RxNorm, and these need to be part of the ultimate solution to enable automated decision support and assessment for research. The idea of collecting semantically rich tagged data elements has been the pursuit of HL-7 for a couple of decades now, and I think the HL-7 enhances the foundation for this universal information exchange and become the foundation for data exchange specifications using XML.

They also point to the opportunity to more efficiently link patients to clinical trials, and I agree with this as well. If we could have a coded core set of pragmatic eligibility criteria, this would help facilitate filtering studies for patients. There's a project in the CDISC protocol representation group addressing this, and it mentions the opportunity for surveillance in public health, again, the common coded data would be required. It's a major obstacle to capturing this in a busy five to ten minute appointment though and the emerging role of a chief medical scribe may be an interesting one that a physician extender ....

My last comment is in terms of the universal patient identifier. I'm of the mind that this will be needed for such universal record linkage as a major hurdle to have the correct matching, and I don't believe that identity resolution techniques alone and technologies and probabilistic matching will be sufficient specifically for ... medical research. While I think PCAST is a great start, what is proposed is not fully sufficient and we need a complete semantic framework, a common data model, terminology services, ontology rules expression language, and identity resolution capability. Thank you.

William Stead – Vanderbilt – Chief Strategy and Information Officer
Thank you, Joyce, 16 seconds ahead of schedule. How's that? That's the winner so far this morning in addition to the very thoughtful comments. As I reflect on what I read and what I'm hearing, there's clear interest in an ability to have more access to information, to manage data at the population level, and to actually manage the connection between population management. And the quality concern of managing an individual as a member of a sub-population so that I know whether I'm in fact getting the outcomes for the individuals under my care that I should be. At the same time, there are concerns around the validity of the sample sets that we would get with the various consent provisions. In addition, the willingness to participate, so will in fact the approach proposed by PCAST lead to sample sets that we do not know how to interpret from a population basis, and similarly from a semantic basis, will the difficulties in semantic interoperability lead to misinterpretation? I think those are the themes going into that.

Let me probe a second, because Richard I like what you're doing in the distributed management, and I would envision that as continuing if PCAST were fully available. I actually don't read them as an either/or; I hear them as an and. So I actually come back and ask a question, what might you be able to do, what you or the participants in these distributed centers that are cleaning up your data, what might you be able to do if you had a PCAST style infrastructure sitting alongside what you have today? What could you do that you can't do today that might help you?

Richard Platt – Harvard Medical School – Professor & Chair
The guiding principle I think is that what's important for these population measures is information that's really divorced from data about individuals. So the goal, in my view, is how to obtain the information that we want without having to move information about individuals from the location where it exists. To the extent that that's what PCAST was saying, I didn't appreciate that as the direction that the report is going, because it would be necessary to have sufficient participation by the distributed organizations in their willingness to participate in that deeper interpretation of their data and understanding how systems differ from one another in the way they record information. It would be necessary for them to be willing to participate in receiving and implementing what can be a substantial number of computer programs that are querying their data and for which there's a non-trivial amount of follow on questions about the nature of their data that would need to be engaged. So it's not just about the data. There has to be, at some level, a real partnership by the holders of the data.

William Stead – Vanderbilt – Chief Strategy and Information Officer

Understood. I won't do this as a back and forth, so let me start with—

Richard Platt – Harvard Medical School – Professor & Chair
Could I also say part of your original question had to do with perturbations of the data sets by requiree consent, and here I think it's really important to make the point that there are enormous threats to the validity by using information that's restricted to those who volunteer. As a society, we're going to have to find our way to a safe position in saying it's acceptable for my healthcare provider to provide information that says something along the order of we had 53 men aged 60 to 64 who had a colonoscopy and this was their outcome. That my data would be able to contribute to that without my consent because without doing that, I think we're at serious risk for obtaining flatly misleading results.

William Stead – Vanderbilt – Chief Strategy and Information Officer
Wes, would you like to start the questioning by the workgroup?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Thanks. I'd like to confirm and maybe just a little bit extend my understanding of your proposal, and then I want to ask an off the wall question. If I were to summarize your approach, or the approach described in your testimony, and send a question to the data in a sense of distributing a program to operate within the privacy and security things operated by the provider who has the data or the other ... has the data, it strikes me that that's already something that's done not necessarily with a tight technical fabric, but it's done among researchers because they really don't want to share their data. If another researcher asks for some information drawn from their data set, they're more willing to do that than they are to say here's the data. I'm not advocating for researchers' ability to hold on to data, but I am saying that it appears to be an approach that's in use now. Is that correct?

Richard Platt – Harvard Medical School – Professor & Chair
There are a number of examples of distributed analysis systems that are up and running. I listed four of them in my testimony. That's not really a question of researchers' unwillingness to share data so much as the data holder's unwillingness to share data, and a large component of the reason for being unwilling to share the data is the concerns about threats to privacy and confidentiality.

William Stead – Vanderbilt – Chief Strategy and Information Officer
Craig?

Craig Mundie – Microsoft – Chief Research and Strategy Officer
Just one quick question. I've been listening to everything that's been said about privacy and consent for research and what I cannot get straight in my head is what in this discussion compares to the role of the IRB in current research? Is that just an old fashioned thing we don't need any more? I'm sorry to ask such an off-the-wall question.

Richard Platt – Harvard Medical School – Professor & Chair
No, that role persists. IRBs have just as important a role in a distributed environment as they do in any other.

Joyce Niland – City of Hope – Associate Director & Chair, Information Sciences
If I could just comment, I agree with the concern about the validity of the sample. Without having biases due to opt-out with consent for the national outcomes research study that we're doing, the IRB is playing the role at each center of determining whether patients are allowed to opt-in or out to consent, or this is an important quality assurance process and every patient's data elements will be included. The split is about 30% of the centers around the country are requiring consent, and about 70% are saying this is a quality assurance and ... validity of the sample size all patients' data will be included. Of course, we have a lot of safeguards for privacy and not reporting any individualized data and being careful with that. But it's a real problem for the validity of the research, I agree. When we do require consent we ensure that at

least 70% of the population at that center is agreeing to opt-in, otherwise we won't utilize the data as potentially being biased like the sample.

William Stead – Vanderbilt – Chief Strategy and Information Officer
Thank you. Craig, would you like to make a comment or a question?

Craig Mundie – Microsoft – Chief Research and Strategy Officer
Yes, Bill, just briefly. To Richard, I looked at the five things that you said, and in a sense I wanted to agree with Bill because many of his comments were what I was originally going to say. I think PCAST is silent really in the recommendation relative to at least four of the five principal things that you say, and I'll just go down them, logistical complexity you could say that the report begs the question of how do you operationalize the analysis from a computing point of view. The report doesn't actually dictate one way or the other, so, as Bill said, I think it would be fine to think that it could live alongside a distributed analysis model, or any other particular model that might be appropriate. The report speaks mostly to how would you find the data that you want to analyze, not that you necessarily have to force it into a particular place or mode for analysis.

I think also, going down the list, the threats to privacy really comes to the policy questions, as does the reluctance of people to hold the data these last comments, and again PCAST I don't think speaks to that. It says we advocate the creative mechanism by which any of a variety of policies can be implemented with respect to the secondary or tertiary uses of data, but we don't speak at all about the policy. So the intersection between population and research requirements and that of the preference of the patient is a policy choice and our goal is to try to say that there's a mechanism that could essentially reflect those policy choices. Whether they be strictly by the patient or whether they be superseded by some kind of legislative or national policies as it relates to population health, and the report is silent on that as well. I think that most of the things that I read here are policy choices which we thought to be able to implement, both as it relates to privacy, aggregation of the data, and even the mode of computation. So I don't think that they're in conflict actually with the goal that you stated.

Richard Platt – Harvard Medical School – Professor & Chair
I'm delighted that that's the case. I may be the least expert person in the room about privacy issues, but it's important for us to realize that for a number of the kinds of studies that we're talking about, the amount of data for an individual that's required is just about everything there is. It's not a single prescription or a single laboratory test in order to compute disease risk scores or do propensity score matching, it's important to have years of data that has essentially every diagnosis and every procedure. My understanding is that the more data that one has about an individual the easier it is to reidentify. So my sense is that moving that amount of information for an individual is an increased threat to privacy and so we've worked very hard to develop methods that don't require the data to be moved that way. I take your point that it's possible to use distributed methods in the presence of a PCAST type arrangement, but it seems to me that many of the things that the PCAST Report was talking about had to do with constructing data sets almost on the fly, and that will be a very complicated thing to do.

Craig Mundie – Microsoft – Chief Research and Strategy Officer
I think a lot of the comments that we made in respect to this real time construction were more along the lines of providing decision support for care, as opposed to population size aggregations that would be provided. It's conceivable that both could be done, but the report doesn't speak to the design choices of how you might do those things in different ways. If you are trying to get a small amount of stuff together on an instantaneous basis, that might be completely fine. Let's say I want something analyzed for all 300 million Americans, that would be a different matter completely.

One thing I'll say, which was my answer to the question that Bill asked that I don't think you perhaps had a good answer to, which was could it help you with some of your goals? The one thing that the report might actually allow you to do is to find out where there are data sets that might aid and abet the research goal that you didn't know about. Again, you can decide what to do with that information, and of course it's

all subject to the privacy and policy constraints that govern it, but our view was that there may be a lot more data to support research of a particular type than any particular researcher historically had visibility into. So the transparency that comes from having access or just a knowledge that this stuff exists could in the end support the research requirement.

Richard Platt – Harvard Medical School – Professor & Chair
I certainly take that point. Since it sounds as though there isn't so much distance between us in some regards I'd say it would be useful to expand the PCAST Report to make clear that we're not talking about moving years of data about millions of people to address each of many important societal needs.

William Stead – Vanderbilt – Chief Strategy and Information Officer
Paul?

Paul Egerman – Software Entrepreneur
Thank you, Richard, and thank you, Joyce; very interesting issues. It was interesting earlier, Dr. Peel made a comment, she said something like she didn't think the public really understood the whole area of research and she said that ... a member of the public, but this is a fascinating area. I think the PCAST Report has done a good job of elevating our attention to this entire area, because we have been focused almost entirely on patient care issues and the model that you're putting forward of distributed analysis is very compelling and seems like it addresses a lot of privacy and security issues. It also potentially addresses a lot of business and financial issues. One of the things I always think about, is I thought about your model of distributed analysis, and PCAST has this concept of a universal exchange language. Is it possible to expand the universal exchange language to include a universal research language which you could specify these research activities for this distributed analysis, and also is it possible to actually define a data model that works for research? Or, are each one of these studies so different that you really can't possibly do what I'm asking?

Richard Platt – Harvard Medical School – Professor & Chair
I think it will take a while before we know whether a single common data model will support a large fraction of our needs. My guess is that we may converge on to a data model that supports many, many needs, but it's another one of those areas where I think we're in flux. The CDC's Vaccine Safety data link, the FDA's mini Sentinel program, and a couple of the AHRQ comparative effectiveness programs use common data models that are enough alike that I can imagine they're converging. The operational medical outcomes partnership, that Marc Overhage is a leader of, uses a more complex data model and we may come to find that it's useful in ways that the other ones aren't. So I think there's some work to do. The good news at the moment is even for large national programs the work of creating a common data model that supports the specific needs of the program are not terrible. It's not years of work, it's months of work to come to an agreement on those data models. So at the moment I don't think there's a compelling need to try and standardize on one. Part of the reason for that is only a small fraction of the complexity of a medical record is actually needed to address the large majority of the questions that the PCAST Report names, and which I think are at the center of our needs.

Joyce Niland – City of Hope – Associate Director & Chair, Information Sciences
I'd agree that I think a common data model is going to be really important. However, there is another emerging model, which is the BRIDG, the Biomedical Research Integrated Domain Group model, which is a collaboration across HL-7 ... Standards Living Group and the NCI caBIG program. I think we do need to eventually come to such a common data model and I don't quite see how we are going to have this exchange of data across the many different providers and systems to meet the majority of research needs. I also think Richard's idea of a distributed analysis model is very interesting and can meet quite a few needs. But I think for some studies you are going to need a prescription data store that does actually move and aggregate and accumulate data over time for certain individuals I think some things can be done, distributed ... can be done in real time such as clinical decision support. Some of these outcomes research studies, in my experience, are going to require more of an aggregated data store.

Craig Mundie – Microsoft – Chief Research and Strategy Officer
Sorry, ... distributed analysis do you do a different data model for each study? Is that what you're saying?

Richard Platt – Harvard Medical School – Professor & Chair
No, I'm saying that in different programs we haven't yet felt the need to insist that the data model used for the AHRQ comparative effectiveness work be exactly the same as the data model for the FDA's mini Sentinel. They're close enough that they could be made to converge, but because we're in early days it's been our view that the data holders and the evaluators should devise a data model that they think will suit them best. I've been involved in several of these and we've allowed a certain amount of flexibility in their implementing those.

Craig Mundie – Microsoft – Chief Research and Strategy Officer
The other part of my question is, is it possible to create this thing I call a universal research language, which would be how you would specify the distributed analysis and perhaps use some of the concepts from the PCAST Report in it? Assuming ONC establishes the various standards for metadata you could at least have a standard way of expressing the specific data elements needed in each study.

Richard Platt – Harvard Medical School – Professor & Chair
Possibly. I'll take us back to Marc Overhage's comment about requiring in-depth knowledge of the source system. So my caveat on developing this standard language is that for the time being it's important to have the originators of the information participate in the interpretation of the information because between practices providers can preferentially use one set of diagnoses over another and they're both right. And unless you understand that they've made those choices you can misinterpret the analyses that would result.

Joyce Niland – City of Hope – Associate Director & Chair, Information Sciences
I agree that it would be ideal to have some elements that are specific to research, but just for the opposing view, I think in general we need to be moving to a common data model across clinical and research for the sake of global population based research. Otherwise, I don't see how it's ever going to be practical or feasible to have sufficient information across all the various stakeholders. Certainly, it should be a collaboration with the holders of the data developing those models, but to me if we don't move to a common data model that allows secondary reuse of clinical care data for research we're going to be missing a great opportunity.

William Stead – Vanderbilt – Chief Strategy and Information Officer
John?

John Halamka – Harvard Medical School – Chief Information Officer
Dr. McCallie's been waiting longer than I. I'm happy to defer the floor to him first.

William Stead – Vanderbilt – Chief Strategy and Information Officer
We're trying to make sure we deal with the working group first and then we will get to—

John Halamka – Harvard Medical School – Chief Information Officer
Okay, I will make this very quick. I'm absolutely a fan of federated models, it's everything I've ever worked on, but some could argue that federated models may be institution centric as opposed to patient centric. So imagine that I start taking a diabetes drug, I'm seen by one doctor and one hospital and then I go across town to a competing system where I have my heart attack. So hence since a federated model may ask a query about a data set that may be institutional and specific, if the patient crosses data sets you may not be able to do that computation, so some would therefore argue, oh, centralize and then we can do much more accurate linkage of patient events.

Richard Platt – Harvard Medical School – Professor & Chair

That's a very important issue. The specific example you gave is one that doesn't arise if you work with data that's held by health plans or insurers because they know about most of the medical events, at least for which there's a financial transaction involved. I think the real frontier in all of this work, including distributed analysis, is in dealing with what I learned is called vertically partitioned data, having individuals' information scattered across systems. My hope is that the evolving field of analysis that can deal with vertical partitioned data will let us avoid putting those data together. There's a meeting tomorrow of the working group ... to talk just about that topic and what its prospects are and what it would take to implement it.

M
The Markle Foundation did some work with Jeff Jonas, who solved it for Las Vegas, and if we can solve it for Las Vegas, we can solve it for healthcare.

Joyce Niland – City of Hope – Associate Director & Chair, Information Sciences
But what happens in Las Vegas, stays in Las Vegas.

M
This is the cross-Casino identifier without having to disclose the actual demographics of the identified ....

M
It's more than just knowing that the same individual's in both places, but being able to do a reasonably sophisticated analysis without moving any of the data elements. That's the real challenge.

Joyce Niland – City of Hope – Associate Director & Chair, Information Sciences
But as long as you do have a patient centric view, as you were saying, rather than an institutionally specific view that uses different vocabularies, semantics and meanings across different centers you won't be able to combine the data in that case.

William Stead – Vanderbilt – Chief Strategy and Information Officer
Have we dealt with the questions from the working group? Wes has come back to the floor.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I want to raise attention to this notion of a universal data model for research data. I've been working in interoperability models for a long time and what I find is that our notion of what the model should be advances at least as fast as the model. Our ability to roll out that notion across databases with five or ten years of data is usually limited by they have to wait until you have all the data in the database. I think that there's some research already in place that is very relevant, and that is several academic institutions have been looking at combining data from the 200 or so typical ... number registries they have of purpose specific data collected under IRB approved projects. That the data model, if you will, in a more abstract sense, associated with the semantic web and with reasoning tends to be very handy at letting them find an easy way to combine data across registries even though the data models for individual registries are different. I think there's some resonance with that and some of the concepts in the PCAST Report. I'd be interested to know, has that issue of combining data across registries come up for you? Are you aware of that being an area of general research right now?

Richard Platt – Harvard Medical School – Professor & Chair
Joyce, do you want to go first?

Joyce Niland – City of Hope – Associate Director & Chair, Information Sciences
Sure. We have looked at this quite a bit ourselves also and it still is a challenge because of not only the semantics but also the rules applied during the data collection process, the directives often differ. For example, we wanted to use cancer registry data for our outcomes research study in oncology but the way of defining a diagnosis was totally different from the outset and the cancer registry. They would define the diagnosis as going back to the first symptoms of that diagnosis after the final pathological

confirmation, versus in the outcomes research we were just looking at the final diagnosis in its confirmed date and result. If you don't have similar semantics and rules at the time and the date of the collection sometimes it's impossible to do the mapping. It's a very valid goal but it can't always be done depending on the rules and the definition directives under which the data was collected in the different registries.

Richard Platt – Harvard Medical School – Professor & Chair
The one experience I've had trying to do the cross-registry evaluation was in working with information from state immunization registries around the H1N1 influenza vaccine. There we found that even though there was a high expectation that the registries would be capturing the same kind of information in about the same detail, that there was a substantial variation across them and so because this was a problem that couldn't wait, we adopted a lowest common denominator approach to assembling their information.

William Stead – Vanderbilt – Chief Strategy and Information Officer
Thank you. My peripheral vision is not failing again, and we're ready for David.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Thanks. It's a great discussion and like the privacy one could go on, I assume, for days. But when I think about large scale databases that are captured as a side effect of providing care, be they federated or centralized, that's not the point. There's the data that's out there, the utility for the research agenda to me has always seemed to be on the side of exploratory data analysis and hypothesis generation, rather than actually being able to conduct a study. The reason for that is in large part what's been discussed already is this semantic mismatch. Not everybody's capturing the data with sufficient agreement on the meaning to justify its use in the study, and part of it is just the granularity of the data that's captured in a ten minute encounter, the average practitioner is not going to capture enough data to drive many of the studies that need deeper analysis.

I wonder if the PCAST vision should be one that's really thought of primarily as supporting exploratory data analysis and hypothesis generation for which random opt-outs is not a problem just because of the statistical likelihood, as you're going to still sample enough to generate your hypothesis. Then for actual testing, you have to do a more controlled study and if you have a common data model that's a good start. But you then have to agree on common semantics for the data elements that are captured and you have to agree on getting people to actually capture them under the understanding that it's part of a specific hypothesis to be tested. The notion that we could do all of those things with a single database seems far-fetched to me.

Richard Platt – Harvard Medical School – Professor & Chair
Okay, so that was a pretty simple question.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
They gave me so much time to think about it.

Richard Platt – Harvard Medical School – Professor & Chair
The issue here is to what use can observational data be put, and the answer I think is it's terrific for certain kinds of questions and can answer the question as well as can be answered. There are other situations in which it can provide useful hints that need to be followed up. And sometimes it's not useful at all and you just shouldn't ask the question even though it is mechanically possible to process the data. I think it's essential that you bring the knowledge of both the question and the data together to understand whether it's worth doing that. It is, to my mind, impossible to use anything other than observational data, to answer the question why does smoking cause lung cancer. There are a number of situations in which I think one might be persuaded that the observational data are both detailed enough and free enough of bias that you might give good weight to the answer that comes out of that. I'd be happy to provide some examples of those situations. Some of them are ones where there are experiments of nature, where there's an abrupt change in therapy and there's no plausible reason to expect a difference in outcome that would be associated with that.

So there are lots and lots of reasons for doing that, but I think in almost every case non-random dropouts are a threat to validity. I think it's insufficient to say just because there's a large number you can infer something useful for that. If you know a lot about who the dropouts are, it's conceivable you can account for them. But particularly in a situation where you don't know what the dropouts are, I think it's an invitation to a serious misunderstanding of the results.

Joyce Niland – City of Hope – Associate Director & Chair, Information Sciences
I would agree. Your comment about exploratory and hypothesis generating is one very valid use of this data for the reasons such as the dropout and the bias involved. There are other types of research we haven't discussed either that is of great interest for the general population, just patterns of care, the uptick of new practices that are being discovered through clinical trials, and how quickly are they moving into the general healthcare arena concordant with practice guidelines can be studied out of these large population based databases. Of course they don't obviate the need for clinical trials when you're trying to look at new drug discovery and testing, but we all know that in clinical trials those are biased samples also, that you generally get much better outcomes under those controlled narrow eligibility criteria. So just looking at the general complications and the ability to achieve effectiveness in a broader patient population is another good use. I totally agree with Richard that you have to match the type of data and how it was collected with the type of usage questions that you're trying to answer.

William Stead – Vanderbilt – Chief Strategy and Information Officer
Thank you for that.

M
Richard, the model you're talking about, I like how you're very clear about the role of the data sources as partners rather than mere sources of data, and the comments about how they really need to be involved in understanding whether the data that they have can be suitable for that and to design even the question. It seems to imply a carefully curated, relatively small number of sophisticated institutions, a dozen, two dozen, that can serve that distributed research engine function. What do you lose? What is the biggest loss from this approach versus something that's a little more proletarian that has more standardized data models on less sophisticated edges that can be implemented more successfully by a larger number of participants?

Richard Platt – Harvard Medical School – Professor & Chair
I think we need both. We, and I too during this conversation, have sometimes used the shorthand of "research," whereas, we're talking about research, we're talking about the public health practice, we're talking about quality assessment, so for doing quality of care everybody has to play. To assess the risk of serious neurologic complication of meningococcal vaccine, maybe you only need ten very large organizations that can bring a substantial fraction of the U.S. population to bear, but not everyone. So once again I think it depends on what the use is. Syndromic surveillance, where you let a lot of the thinking of that is another that has to be where the syndromes are and not where the data are. I think in some of these situations you can do it very well with limited amounts of data, where the concerns about nuanced interpretations aren't so important.

William Stead – Vanderbilt – Chief Strategy and Information Officer
Thank you. Chris?

M
As many of you know, I've focused, as have many in this room, on the problem of the use of clinical data for research. And I guess this will be a question eventually when I finish, among the things we've discovered is that there are two impedance mismatches between research and clinical data that bear attention. One of course is the perennial objection research moves too quickly or we can't be constrained by existing standards as a way of representing our data. The second is what I would characterize as the granularity dissonance, where historically data that you would collect in a rigorous protocol is

excruciatingly detailed and well characterized, whereas, what you would casually put down in a clinical encounter may not have that rigor in terms of its structure and in terms of its completeness and in terms of its literally protocolized entry.

That being said, I think it's fair to observe that a lot of the clinical data that we are collecting has what I would characterize as wanton idiosyncrasies. Where we choose arbitrarily to represent why every laboratory in the country has to have their own lab codes is beyond me, for example. Why every vendor in the country has to make up their own schema for the way we represent similar data is beyond me. I think we as a country, or as a planet for that matter, wearing my ISO hat, could go quite a bit further to reducing or at least mitigating what I would characterize as these wanton idiosyncrasies in which case the whole notion of federated data structure, of secondary use of data in an observational context I think would be hugely leveraged in terms of its quality, efficiency, consistency and comparability across a broader spectrum of proletarian, if you will, use cases.

So the question is, to what extent do you think we can achieve progress, either through the PCAST model, through federated data structures, through progress with meaningful use implementation, through a variety of mechanisms that we have control over, to some extent, to achieve this goal where the secondary use of data for legitimate research discovery and new method or new care identification or risk identification, you know the use cases as well as I, can be enhanced by really implementing not models that are different just because they can be different, and Sentinel and some of the other AHRQ models are good examples, but rather models that choose in a national consortium to actually, and BRIDG comes to mind as founding chair, as ways of saying gosh, why can't we represent information consistently and comparably and why don't we propose these as shared goals to achieve that effort?

Joyce Niland – City of Hope – Associate Director & Chair, Information Sciences
That's exactly right, Chris. That's where we need to go as a nation and as a planet, as you say. I think it's going to take a carrot and stick approach. I think we're going to have to use some of these mandates of meaningful use, reimbursements and other incentives to ensure that people eliminate these wanton idiosyncrasies, as you say, and have some standardized coding for some key elements, some enterprise wide elements that we all are going to need for the public health and for quality of care research and other purposes. I don't think we're going to get there otherwise. And that's another reason I think this will be very difficult to achieve in the 2013 time frame. But I think it is achievable, other countries have done it, and I think we really need to bite the bullet and have some of these mandates in place for key data elements and data model structures.

Richard Platt – Harvard Medical School – Professor & Chair
I sign on to that proposition too. The couple of caveats that I have are that for the programs that I've been involved in it's been important for us not to let the best be the enemy of the good. And so we've recognized that we can't take a comprehensive approach to standardizing all of the data, and we've said these are the 60 data elements that are most important to us and we'll deal with them. Because we realize that at least at the moment we're making decisions that aren't hard to change later on, we said we're not going to delay very much longer in order to get going and developing the methods for doing this knowing we can make the translation later on. But those are two small points that are largely operational, I'd say, as part of the journey to the destination you've described.

Joyce Niland – City of Hope – Associate Director & Chair, Information Sciences
That's another key word that Chris mentioned is "granularity." We really have to agree upon the level of granularity needed for certain of these terms and elements without impeding care and making it too difficult, but yet you can always roll things up to less granular but you can't capture it if you don't obtain that granularity to begin with.

Richard Platt – Harvard Medical School – Professor & Chair
I just want to say that it's important for us to realize that once we achieve that we still won't have ended the need for being very thoughtful about the application of specific questions to specific data sources.

They evolve so rapidly that even the widely agreed common data model won't assure that the information representing them is really mutually interpretable across sources or across time. We're just going to have to be vigilant to make sure that we don't make inappropriate conclusions that arise from changes in practice that are completely unrelated to the question that we're actually intending ....

Joyce Niland – City of Hope – Associate Director & Chair, Information Sciences
In my other head is a ... and I totally agree.

William Stead – Vanderbilt – Chief Strategy and Information Officer
Thank you. I see that questions have been dealt with, so let me summarize what I believe I've heard as the major themes that we want to carry forward. I think they really are two major categories. The first is that we want to be clear that PCAST does not preclude and it in fact supports the ability to aggregate a persistent set of data and to curate it for specific purposes. There are a number of sub-bullets that fit under that that relate to our ability to correctly interpret the data, so that the idea that we might be able to have a universal data model to support research but that research data is different; observational data tends to be continuous, research data tends to be discrete interpretation of that data. The semantics that we currently have require the sources to participate actively in the interpretation as we curate it. So that's one bucket of things we need to pay attention to as we understand our alternatives.

The second is the fact that we've got to be careful about the use of granular criteria for consent and the willingness of different organizations to participate or not. We've got to make sure that we manage those very valid needs in a way that also allows us to get the proper numerators and denominators as we're really understanding how the patients we study fit into the population as appropriate to the purpose. I think those are the major themes that we've got to work carrying forward. So I want to thank Richard and Joyce and the committee members for the thoughtful questions and comments.

Paul Egerman – Software Entrepreneur
Thank you very much. Thank you, Bill Stead. We are now breaking for lunch. We'll be back at 1:15. Thanks.

(Lunch Break)

Paul Egerman – Software Entrepreneur
So, are we ready to get started again? Good afternoon. This is the afternoon session of our PCAST Report hearing and this is panel number four, Providers and Hospitals, which is moderated by Steve Stack. I don't see Steve anywhere, but we will go ahead and get started. All of our panels are great. This is a great panel. But this is the greatest panel after lunch ever in the history of the federal government, and it's going to be five people on the panel. What we're going to be doing, because we have five people, we told you this in advance, is you get three minutes. There was a comment this morning on the timing that somebody said I had been ruthless, and I was really very proud of that comment. So we will continue in that entire path. In order to get started, and unfortunately the moderator isn't quite here yet, but we'll go ahead and get started, I'm going to ask you to just spend a minute first and each say a sentence or two and introduce yourselves, so we'll start with Sarah.

Sarah Chouinard – Primary Care Systems, Inc. – Medical Director
I'm Sarah Chouinard. I'm a rural family practice physician. I practice in central West Virginia. We have about nine counties that we serve, which is a lot of West Virginia. And we are using an electronic health record that's also used in Terry's shop. We use IHS' solution RPMS, an open source solution, and have an open source PHR that we're using in all of our practice locations.

Paul Egerman – Software Entrepreneur
That's great. Scott?

Scott Whyte – Catholic Healthcare West – Vice President, Clinical Systems

Scott Whyte with Catholic Healthcare West, CHW, and I'm a Senior Director within IT. We use middleware as a health information exchange solution to connect with our community physicians.

Terry Cullen – Indian Health Service – Chief Information Officer
Good afternoon. I'm Terry Cullen. I'm a family medicine doc. I happen to be the Chief Information Officer for Indian Health Service, and in that role we're a software developer, deployer, supporter, and public and population health contributor.

Paul Egerman – Software Entrepreneur
Terrific. And so we'll start with you, Sarah.

Sarah Chouinard – Primary Care Systems, Inc. – Medical Director
Sure. Thank you for affording me the opportunity to attend the meeting. I appreciate it. I want to use the generous time that I have to discuss really just three salient points. First, I believe that we're making a mistake if we don't begin engaging patients to understand and to demand health information technology. I see patients as the accelerator in HIT adoption. Second, I'm concerned that if changes in reimbursement to support this new method of care delivery don't occur soon enough, that we're not going to see ongoing use of HIT by those clinicians that have taken the steps to adopt it. And third, I think the federal government has an opportunity to close the digital divide that exists in communities who suffer from a lack of resources by providing those practices and their patients open source solutions for both HIT and HIE.

I think that while we're developing standards for data exchange we should be giving tools to patients to help them understand the goals and the advantages and the plans for HIE. In the absence of an accelerator for the adoption and effective use of HIT by practitioners, there may be limited meaningful data to be exchanged. From my personal experience on the front line with technology intersecting with personalized healthcare, I think patient engagement and the use of data and personal health records will be the driver of the rate at which the healthcare system embraces HIT.

In our practice we use an open source, Web-based, CCD data extracted, vendor neutral personal health record. Any EHR can be interfaced to a network of PHRs and patients can be controlling data that's shared across the healthcare system right now. By placing patients at the center of the exchange process it could occur at the same time that these other agencies, ONC, CMS, HHS are all meeting their objectives. If patients are not demanding access to data, we're less likely to give it to them. Right now patients do demand medications, they demand education, treatment, but they haven't yet started to demand technology. I think we need to engage them right now, so an opportunity exists for ONC and CMS to offer a default solution for patients and providers who either would not or could not keep up with the digital evolution. Open source tools should be incorporated into the HIT infrastructure. ONC, CMS, and other agencies must make sure that we offer solutions for patients and providers who are already suffering from the barriers to receiving and delivering care. These areas suffer from health disparities and we need not have there be a disparity based on technology as well. Thank you.

Paul Egerman – Software Entrepreneur
Good. Thank you. Is John Mattison on the phone? He's still at lunch. So next we'll go to Scott Whyte.

Scott Whyte – Catholic Healthcare West – Vice President, Clinical Systems
On behalf of our 41 hospitals in Arizona, California, and Nevada, CHW appreciates the opportunity to submit testimony regarding the PCAST Report. In addition to our hospitals CHW is proud of our network of over 10,000 affiliated physicians and more than 54,000 employees. We're proud to be part of a healthcare ecosystem in the communities we serve and partner with physicians and providers to create care networks. The vast majority of our facilities work with independent, not employed physicians. This means that in addition to investing in hospital information systems, CHW has to ensure there's sufficient connectivity available to our community physician partners.

CHW has 26 hospitals live with cloud-based middleware information exchange, including 2.5 million patients and over 2,300 physicians. Today within our exchanges we currently transform HL7 version 2 messages into XML and then we already conduct some limited metadata tagging. Much like the majority of the healthcare community, we're making tremendous investments while absorbing enormous costs associated with the implementation of a number of other initiatives, including meaningful use, ICD-10 and 5010. All of these requirements amount to enormous cost, workflow changes, policy and procedure updates, and re-training of tens of thousands of employees while our hospitals are struggling to survive in a difficult economy, amidst drastic changes in the delivery and reimbursement of care.

So though CHW supports the vision and the goals of the PCAST Report, we have significant concerns about the immediate feasibility and efficacy of the recommended approach. CHW ultimately believes that any change in systems approaches is fundamentally a human process. Even with the most advanced technology, implementation and usage of the technology is determined by how it is embedded in policies, culture and workflow. We caution that the legal, cultural, and workflow frameworks are not yet mature enough to disseminate the kind of revolutionary changes envisioned in the PCAST Report in the short amount of time ... prescribe. We agree that the PCAST recommendations of metadata tagging deserve further exploration and even piloting, however, we recommend against immediate adoption of the PCAST recommendations. Instead, CHW recommends exploring harmonizing elements of the PCAST recommendations within existing standards. I want to thank you for considering the feedback of community hospitals.

Paul Egerman – Software Entrepreneur
Thank you, Scott. Next we'll have Kevin Larson. Kevin, can you first introduce yourself?

Kevin Larson – Hennepin Co. Medical Center – Associate Medical Director, Informatics & CMIO
Hi, I'm Dr. Kevin Larson. I'm the Chief Medical Information Officer at Hennepin County Medical Center in Minneapolis. We're a public teaching hospital with a fully deployed electronic integrated health record. Our vendor is Epic. I was asked to represent the vendor-based approach in interoperability, in our case Epic's Care Everywhere. This is a software module that allows point-to-point provider exchange of individual patient's records in real time. We send ... care records over the Web enhanced with granular diagnostic and lab data and counter information medications and provider's clinical notes. Nine large Minnesota provider organizations with medical records of 75% in Minnesota went live with this solution over a year ago. Many other Epic customers across the U.S. also exchanged records using this system, and in the last six months my hospital has seen nearly 1,200 of these exchanges a month, accounting for nearly 3% of our overall visits. These are largely from our own state and encompass 15 different health systems from across the country, as far away as California. We have many examples of enhanced care and reduced cost due to these exchanges.

It's no accident that Minnesota is a state of early interoperability. We've been working for many years toward an interoperable electronic health record with the state goal of 2015. By articulating this goal and committing to it our provider community has invested early in electronic medical records, favoring those vendors that support integration and interoperability. We have a number of public and private forums where we've established a shared set of data standards governance in the security framework. In fact, I serve on a state committee much like this.

In addition to Epic's Care Everywhere, my hospital and others in the state are interoperable with a radiology pack system, joint clinical decision support platforms, ePrescribing, immunization registries and multiple other administrative transactions. I believe that Minnesota and the Epic vendor community have achieved its revision of a patient centered health record where consumers are in charge of their information, ... organizations to deliver health information to our patients who want and expect other partner organizations.

We are currently giving automatic access with appropriate roles and authentication credentials via the Care Everywhere solution. A couple of key issues arose that we needed to address. First has been our

liability to breach by another organization. This has been no small feat. Second is our ability to stop the flow of data or sanction an organization that demonstrates this breach. These are groups that we previously have not had data use agreements with. Currently with the passage of federal and state laws we need to exercise considerable control over access to our EHR data. We are especially cautious because a liability case law has not yet been established and we are concerned about the full disclosure provisions of ARA and our ability to disclose access to our data by members of other organizations. To date we have chosen an all or nothing approach to interoperability and any patient that chooses not to have part of their record exchanged goes through a manual human process.

Paul Egerman – Software Entrepreneur
Thank you. Admiral Cullen?

Terry Cullen – Indian Health Service – Chief Information Officer
You got done in time, Kevin, and you missed the threat of us. I'm going to answer these three questions. And what I do want to let everyone know is we have to fill these in 35 states over 400 sites, both tribally operated and federally operated, so I kind of bring an amalgam of lots of experience, lots of different states. I'm going to answer the three questions. One is performing information exchange. Indian Health Services has been a leader in performing information exchange. We've participated in immunization exchanges for the past six years. In many of our states we've exchanged over 4 million immunization records. We also have a unit and a bidirectional reference lab interface, and these were stood up long before meaningful use came along.

In addition we have tribally operated sites that perform information exchange with what used to be called HIEs on a regional level. The reason why they were able to do that is related to data sharing and federal ownership of data. The tribally operated sites do not fall under many of the constraints that affect the federal site, however, given that enormous experience we've had multiple challenges, they include the inability of states to stand up what needs to be stood up, the lack of infrastructure related to standards, the implementation of standards, depending upon where your site is, so we have a success story there. But we do not have an enterprise wide success story because we're in multiple states. If we were only looking at one state we would be able to say we were more successful.

If we move to the next question, which was really related to automatic access, those of you who are familiar with our agency, we are an operating division with Health and Human Services. We want to participate in the Nationwide Health Information Network Connect. We technologically can participate, however, our users are consumers and have voiced innumerable concerns about the data use agreements, the current ... as it stands, and it's all related to reuse. It's not related to sharing data specific for consent, for treatment, and for payment purposes. It is for the potential of reuse of data even in situations where there may be benefit to a specific community, i.e. in American Indian and Alaska Native tribes. That has made us proceed in a reticent fashion to engage in interoperability and sharing of data, that we are not sure that the consumer has given appropriate consent for.
Finally, let me go to metadata and tagging and attributes. Actually, our data that comes in from our immunization exchange is tagged. It has an attribute that is an outside source of data. Regardless of it being an outside source of data we use it for clinical decision support and for projection. Our providers know that that data didn't get generated natively and we also take in historical data from other sources that way. I believe technically this can be done, I want to echo what Catholic West said, however, in the face of 5010, ICD-10, SNOMED and every other standard that is hitting us right now to give to the vendor community and the provider community another standard will be very difficult.

Paul Egerman – Software Entrepreneur
Thank you very much, Terry. John Mattison from Marshfield.

John Mattison – Kaiser Permanente – Chief Medical Information Officer
I'm going to actually change a fair amount of what I wanted to say, because so much of it has been so well covered by some of the other presentations today. So what I'd like to do is just highlight a couple of

key things that I think have been addressed already and then focus on some considerations that I don't think have been as exposed as they might.

The first is that whenever you design anything, whether it's a database or a semantic representation model, the outcome really is largely determined by what your priorities, your objectives, and your key assumptions are. Wes Rishel has educated me on this for about two decades now, and I'm a firm believer that in semantic representations there's a classic tradeoff between expressivity and reproducibility. So you can focus exclusively on expressive richness, you can focus exclusively on reproducibility, or you can strike a balance depending upon what problem you're trying to solve with the database or the semantic representation. So in that classic tradeoff I think that there are some serious considerations that come into play in this context. Existing semantic constructs prior to the PCAST proposal were very much focused on the primary objective of direct patient care, while not abandoning the objectives of secondary uses of data for data mining research and so forth. I think the PCAST approach to atomic level data and metadata is towards the reproducibility end of the spectrum at the expense of expressivity and I think as a result it would be a tremendous value add for secondary purposes but at somewhat of a cost in terms of expressivity.

The second thing I'd like to highlight, and both Paul Tang and Jim Walker have spoken to this eloquently already today, but the document is not an artifact of the paper world. The document is actually a construct of a constellation of findings, recommendations, diagnostic approach, therapeutic approach, that have a coherence and an integrity to them that if abandoned, or if subsumed under a single blob as just another atomic element really leaves a lot of semantic value on the table. So I think it's really important to recognize that contextual information in a document model is really not a derivative of a legacy paper world, it very much represents the way a physician and a clinician thinks about what's in front of them. When they review a chart and they want to understand, well, why did doctor X six months ago do the following treatments and diagnostic tests, and it's very much embedded in that document that was available to him at that time, so very persistent value independent of the paper world.

The other thing I'd like to speak to a bit is the consumer control over – yes, Paul?

Paul Egerman – Software Entrepreneur
I appreciate your comments, but the three minutes is up, so thank you very much. As was expressed earlier I'm sure you have additional comments—

John Mattison – Kaiser Permanente – Chief Medical Information Officer
Can I make one last point? I'm sorry. I thought it was five.

Paul Egerman – Software Entrepreneur
The way people handle it is when somebody asks a question—

John Mattison – Kaiser Permanente – Chief Medical Information Officer
Okay.

Paul Egerman – Software Entrepreneur
You just act like the question was part of the—

John Mattison – Kaiser Permanente – Chief Medical Information Officer
I can answer the question you asked.

Paul Egerman – Software Entrepreneur
It's sort of like Jeopardy. These are terrific comments, and I very much appreciate that everybody has made the efforts that they have to prepare their testimony. We heard a range of things, we heard Sarah say that patients can accelerate HIT, we heard Scott and Admiral Cullen talk about the time frame and

some concerns about the time frame, and we've heard your comment at Marshfield Clinic and your concerns about context. And those are all very good questions.

Steve is back, the moderator, but I'll ask just one quick question before I let Steve moderate the rest of the panel. But on the topic of the time frame, one of the things that's mentioned and discussed a lot in the PCAST Report that, Scott, you made reference to, is the use of middleware. And I'm just curious, can you talk a little bit more about that. Assume for a moment that we go ahead and we say, yes, we're going to do exactly what it says in the PCAST Report, and yes, it's going to be part of the stage two of meaningful use. That means you've got to get it done in 2013, and the report says that middleware would be the way you would do that. Is that what you would do? Is that a viable solution?

Scott Whyte – Catholic Healthcare West – Vice President, Clinical Systems
So if CHW were required to implement the key PCAST recommendations quickly, in other words by 2013, yes, I see that middleware would be the only feasible way to do so. I cannot imagine that we could upgrade 40 hospitals with their core systems in such a short period of time. So yes, we would want to add PCAST compliant metadata, if you will, sort of add tags using middleware. We do that in a very limited way today, so for instance we might have a lab result that comes out of the hospital that we want to distribute to a community physician, and in some of the legacy lab systems the primary care physician may not be listed in that lab system. You would have the ordering physician and the cc'd physician, but we have to pull that primary care physician information from the registration system, for instance. So in that sense that's a way that we tag result data that we would send out and we would expand upon that methodology, I would imagine, in order to meet some of the PCAST goals.

We wouldn't want to do it that way. We could do it that way but then we'd lose that ability to aggregate and analyze for the front end users, so a lot of the clinical decision support tools we're looking at we need to trigger rules based on diabetics. So we need to have diabetics tagged in our system in a way that the downstream users are also going to be thinking about diabetics. I need to really have that at the front end of our system, not just at the back end and not just as a production of our system for some other user of aggregated data.

Paul Egerman – Software Entrepreneur
I'm interested to learn a little bit more about middleware. Tell me what it's like, is it expensive?

Scott Whyte – Catholic Healthcare West – Vice President, Clinical Systems
There are some challenges, and many of my comments related to workflow and adoption and training. With that in mind, some of the tags may not even be captured in the legacy systems, so there's just a conundrum of how do you get the data to middleware. It's got to be captured at some point. So there's a challenge there. There's also an expense, again representing community hospitals, many community hospitals, there isn't really a middleware solution in place and this, if it were mandated by 2013, or I should not say mandated but if there was an incentive to implement by 2013, then it would be a challenge for many, many hospitals to understand the requirements, select the middleware tool, implement, get that live, and then again operationalize it with all the policies and procedures. It's a very expensive initiative even using middleware, given the other initiatives like ICD-10 and other core elements of meaningful use that we're working on now.

Paul Egerman – Software Entrepreneur
You say challenge ... is it hard to implement? Can you just buy these things and it takes an hour or two and you maybe have to read the manual on it?

Scott Whyte – Catholic Healthcare West – Vice President, Clinical Systems
No, it's tremendously difficult. Some of the difficulty is not in per se the technology, to transform HL7 messages and to tag them and to use XML. That per se is not all the difficulty, although that does take work. But there are taxonomy and vocabulary issues that need to be dealt with, patient matching issues, which are a priority. There are, again, issues with the policy and workflow. You can imagine at a

registration desk of a hospital, that registrar needs to be fully educated on the process of consent. They need to understand it well enough to explain it well to a patient who may not really get it. To allow that patient to have informed consent, that's all got to be done in a way that complies with, in our case, three different sets of state laws, and in some cases there may be union training issues, so many, many elements that need to be brought to bear. It's not a quick and dirty implementation, let's put it that way.

Paul Egerman – Software Entrepreneur
Thank you. That's very helpful. Do you think it's a viable solution? Is it a reasonable solution?

Scott Whyte – Catholic Healthcare West – Vice President, Clinical Systems Well, I guess my recommendations are that we not pursue it aggressively in the time frames. If we had to do it I think again if there were a subset of metadata tags that we had to add, I think if we could, but I would recommend against it in the short time frame.

Steven Stack – St. Joseph Hospital East – Chair, ER Dept
Thank you, Paul. My apologies, I was precisely on time to be 15 minutes late and so I should have used my iPhone for better decision support, so my apologies. I do have two questions. The first question, and I'm Steven Stack, by the way, I'm an emergency physician from Kentucky, the first question for those of you principally I guess who are institution level providers, how realistic is the time frame, and I guess the rapid pace of change necessary to embrace the vision that's in PCAST? And I come at it from the perspective of working in a hospital that's two versions behind the present version of Internet Explorer, the rationale being given as it takes, there are hundreds of clinical systems interfacing and each upgrade is typical, so they skip upgrades because it's not pragmatic. So how reasonable is the pace of change necessary to realize what PCAST envisions?

John Mattison – Kaiser Permanente – Chief Medical Information Officer
If I could take a shot at that. I think the tyranny of the urgent here at meaningful use is something to be concerned about no matter what solution we're talking about, including PCAST. So I think the thing that's really important is to have an understanding of what the end state ought to look like and how can we most rapidly get there in a meaningful way. One of the things that I think that the PCAST model needs to ultimately support, and it can't be done in this time frame, but it's atomic level data and metadata around provenance, the chain of custody of data. If you imagine the problem today of how much medical identity theft there is every year and how much erroneous and fraudulent data exists within source systems, you imagine that being propagated across the HIE universe and then you have a patient who comes to you and says how could this possibly be in my chart. I never did that. I never said that. I never had that condition. One of the prior panels stressed this, how are you going to reel all that back in when it's propagated across the universe.

So what I'd like to argue is that eventually we need to have some level of atomic level data and metadata for the management of provenance to support correction of erroneous data. I also think it's going to be very critical to ultimately have that same level of provenance management at the atomic level to support some of the exchanges that will occur between PHRs and EHRs and I view PHRs as a safety valve for people who want to do micro redaction, there is no provider on the planet that's going to go through a chart and do micro redaction, whereas, a consumer might be willing to take that option as a safety valve for that. Once that occurs the provenance of that data having passed through an unregulated environment of a PHR, it becomes important for the provider to know that data may have been altered or redacted unpredictably.

So I think in the end state, PCAST atomic level data and metadata have great virtue, and I would turn the argument a little bit upside down about how it supports consumer control of other data. I would say rather than allowing the providers to impose that kind of metadata around attitudes and preferences for privacy, which is impractical, that for the most part that would be done by the consumer, in which case the atomic level provenance data becomes an imperative to track and manage that. Can it be done in two to three

years? I don't think so. I think it should be part of the long term vision, but the tyranny of urgency is the tail wagging a pretty big dog.

Kevin Larson – Hennepin Co. Medical Center – Associate Medical Director, Informatics & CMIO
From our Minnesota experience we've been at this about ten years or more working towards our goal of an interoperable medical record by 2015. And we think that we're on track to be there by 2015, but that's with ten years of work behind us and a state that's dominated by integrated health systems.

Sarah Chouinard – Primary Care Systems, Inc. – Medical Director
I would echo that. I think the risk we run is moving this target further than we're all thinking it might be in 2015. If you look at the catch up that everybody's playing right now to try to meet MU by 2011, with these other initiatives that are sacrosanct in terms of time frames that are not in fact coming from ONC but from CMS, I think that the belief that we'll be able to meet a target like what's in PCAST by 2015 may in fact be met if you put everything else aside. The problem is that people can't afford to put the other stuff aside, like ICD-10.

Steven Stack – St. Joseph Hospital East – Chair, ER Dept
One other question, if I may. You touched on it in a different context here, but if you meta tagged these data elements and privacy settings persist or endure. I imagine you could collect whatever data you collect at your own institution but if you went to exchange the data that those meta tagging would apply to certain types of data and it might block it. So if there are certain things blocked out or x'ed out it might endure. One question is, do you envision any problems at the provider level as you need to exchange data to conduct your normal business operations or internal quality or things like that where perhaps those enduring tags could impede your normal business operations, number one. And then number two, do you envision any problems with liability, and I hate it that we always let the lawyers kind of make the healthcare providers fearful, but any concerns about if your data is released to other institutions and then they use that data or someone asserts you released something you shouldn't have or they use it in a way that wasn't consistent, that liability accrues back to you when in fact you were just participating in an information exchange as you understood it, so those are two questions. I hope they're clear enough. Any thoughts on the first one, which is, metadata tagged privacy settings impeding your normal business flow?

John Mattison – Kaiser Permanente – Chief Medical Information Officer
I'll answer the second question first. I think in order to protect against concerns about breaches and not knowing how they occurred and what the original intent was and so forth, I think the provenance, again, at the atomic level becomes very important. To your first question about atomic level tagging around privacy and sensitivity, I don't see how that's practically implementable because of the volume and effort required not just to create it but to maintain it, because there's such a vast inter-individual variation in what people consider sensitive and it changes significantly over time. So I'm not sure that atomic level metadata is remotely implementable for that purpose, but to your second question, I think that provenance can and should be implemented at the atomic level.

Terry Cullen – Indian Health Service – Chief Information Officer
I think the other comment that we haven't worked out is what constitutes a metadata tag. If you go back to what people presented this morning in terms of the contextual nature of information and a context, so you can talk about a medication is the tag related to the diagnosis, to the procedure, to the outcome of the patient, and what are you going to query on? So theoretically you can cut and parse metadata however you want it to be and if the wrong attribute is used to exclude the transmission of that data to the receiving provider there is the chance that there could be an unintentional adverse outcome with that.

Kevin Larson – Hennepin Co. Medical Center – Associate Medical Director, Informatics & CMIO
I'll also say to the comment about tagging discreet privacy items and will they impede our internal business, our internal business is fuzzier and fuzzier with each passing day. As we do collaboratives with other groups, what is our business versus what is interchange/exchange is really hard to know. I think of

Surescripts, for example, in our e-prescribing interface and we're now getting formulary alerts on medications, so is that passing context data inside our walls or outside our walls? If I, the patient, don't want others to know about my HIV status is that information being passed to Surescripts and RxHub? Would that be excluded in an HIV exclusion? Those are the kinds of questions we're facing every day and we don't really have a clear way through.

John Mattison – Kaiser Permanente – Chief Medical Information Officer
Steve, earlier this morning you brought up the example of how would you redact HIV with problems, medications, allergies, associated diseases, free text references to it. So if you imagine, let's just think magically for a moment and say we could metadata tag everything at the atomic level and they could push the button and say, "Take out everything that's HIV related." What would happen is the chart would not only be rendered seriously incomplete, but it would end up being like Swiss cheese and would be dangerous as a substrate for decision support. So even if you could practically implement atomic level, metadata tagging for things like that, when you push that button and redact the chart across the entire spectrum of free text and discreet data how is anybody going to make any sense of that record at all in a multi-systemic disorder like HIV or diabetes or cancer, some of the commonest diagnoses that people have sensitivities about?

Another item related to operational challenges would be in communities that don't have a common health information organization that sort of does some of the normalization that may be required and most of our communities don't have that type of organization yet. I can picture a patient's consent differing depending on the purpose for a particular visit and the site of the visit. If they go to a primary care physician, they may be, perhaps, more open about how they consent. It could even have to do with the education that the patient is provided at the point of the registration. So they may give one point of consent at the primary care physician. A reference lab may be quite limited. A hospital may be more thorough again and I can see operational challenges and how would those be reconciled and when would you see the full record. When do you see 50? When do you see 10%? You wouldn't really know.

Sarah Chouinard – Primary Care Systems, Inc. – Medical Director
That's ... the patients understand what they're consenting to, which I think is the other key point. Is there so much information that we spend an inordinate amount of time explaining the pros and the cons of having a personal health record? That is controlled by them, with their user name, their password. We're not giving it to anybody. It's for their use. The answer is, "Why do I want this?" That's what we hear from patients. "Thank you, but I don't know why I want this," so, a long way to go on thinking about what's going to happen with consent and privacy and exchange of data. They don't understand why they want it themselves and these are bright, informed, educated, engaged patients. I think there's a gap between what we're going to do with it and how we're going to get people to care about it.

Paul Egerman – Software Entrepreneur
Bill Stead?

William Stead – Vanderbilt – Chief Strategy and Information Officer
Actually, that's a good segue to the question. Many of the comments have been quite appropriately around the challenges that trying to move in these kinds of directions might impose. For a moment, imagine that we can leave your existing world and place, so we're not disrupting anything. It's going to be able ... but that there's an opportunity to solve some problems in a new way that may be three, four or five years out on your radar screen because of all of the things you've said. Which things might you be able to solve if there was, in fact, some alternative infrastructure that would be most important to you as a provider organization?

Kevin Larson – Hennepin Co. Medical Center – Associate Medical Director, Informatics & CMIO
Well, I think some use case, granular, metadata tagging makes a lot of sense. We're anxious for that kind of tagging on medications and immunizations and allergies. In some ways that exists and in some ways it doesn't. The platforms aren't necessarily common, even in the places we're exchanging and so if

we can talk about really specific use cases around this I think that it's absolutely in our benefit and I can see it happening quickly. The challenge I sometimes have is that it sounds like mother and apple pie, that we're doing to do everything all at once and it's going to be this gigantic re-work of all of our data and that I don't think is possible in that time frame.

Terry Cullen – Indian Health Service – Chief Information Officer
The one area where we've really looked at data tagging is to ensure we don't miss diagnoses, things that we shouldn't be missing. Diabetics that are diabetics and we haven't recognized their abnormal hemoglobin A1C; hypertensives, who have four elevated blood pressures and we should have caught it earlier. So the way we've been using attribute tagging is looking at something like a vital sign or a measurement, tagging it as an indicator that this person may then have a diagnosis that we've missed that would then trigger clinical decision support, giving to the provider these are the attributes we see in this data set that make us think this patient may have this diagnosis. If you can diagnose them then they will get in control. So I think there are some really early wins here and I think what Kevin said is really right—instead of tackling the universe—and Scott said this earlier too. If there's a way to segment this and look at, to answer your question, what really is going to make a difference, the failure to diagnose we know can have historical consequences for patients.

John Mattison – Kaiser Permanente – Chief Medical Information Officer
In addition to what I've described about its utility for provenance and multiple benefits of that, there are certain data types that lend themselves to atomic level metadata tagging. It's typically those that are sort of automatically generated; that don't require a lot of manual intervention; that are generally specific and reproducible. So I think in the very, very near future where there are going to be tremendous opportunities around genomic signatures and if you look at how genomic signatures are going to be a parcel of every single chart in the not too distant future by virtue of the fact that it's required for decision support to know what drugs will be ineffective or ineffective and which are likely to have an idiosyncratic reaction, which is not really idiosyncratic. In some cases it's genetically based; that when every record has a genomic signature, when every research paper is required to publish the database of the genomic signatures I think that atomic level tagging will be very helpful in that context for decision support.

But one of the implications that I wanted to circle back to an earlier discussion this morning is about identification. When you imagine the physician defendant on the stand saying, "Tell me, Doctor, why did you give that drug to that person when their genomic signature already revealed that not only was it ineffective, but it put them at a high risk of a life-threatening, adverse reaction?" That physician is going to be in the position of insisting that the genomic signature be part of every record and likewise, researchers I think will be bound to the same kind of obligation. Given that, I'd just like to make my perspective on that is that identification is very soon going to be a mythical beast and the identification will be practically impossible in the world of genomic signatures.

I could also picture elements of continuous quality improvement, root cause analysis that would be aided by understanding pieces of data that we cannot mine today, like device for instance. You typically don't have that in any sort of clinical data warehouse that you might want to look at, so there could absolutely be some benefits to having more metadata attached to atomic level data.

Steven Stack – St. Joseph Hospital East – Chair, ER Dept
Wes?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Except for privacy concerns, when it comes to a clinical data interface it's always better to give than receive because you, by definition, are going to give what your system has. You don't have to modify your system to receive what they want to send you. Given that that's true, are there any startup strategies that are not, A, overwhelming with respect to cross hospital implementations that might focus on a specific use case or area of interest that can't be handled through the sort of exchange of specific information in the course of giving care. You could imagine a project—I don't want to say pilot or I don't

want to imply a project that's just an experiment. I mean something that could be started and go on if it continues. Can you see a place where you could start down this road with an effort that's more like a needle point than a snow plow?

Kevin Larson – Hennepin Co. Medical Center – Associate Medical Director, Informatics & CMIO
I'd pick immunizations. Most of us have immunization registries in our states and many of us have started exchanging with those immunization registries. We're already measured on the quality context about how accurate that is and we want a holistic measurement across all of the providers in the state rather than just our own measurement, but we're typically certifying ourselves as an organization. We're not certifying to the state, so we have a high need to receive from the state registry. But because we've done all of this leg work to get that standard kind of submission format we're pretty close to making that a use case that this would all work. I would love the metadata tags, where this happened. How sure are we? Is this a patient report? What else do we know about that immunization information?

Terry Cullen – Indian Health Service – Chief Information Officer
Kevin, if you went off on that too, the other thing that happens with the immunization registry is its refusal and the attribute doesn't normally come across what is the cause for the refusal; leads are going elsewhere or egg allergy or whatever. So there would be a way to delve into a fairly pre-defined set of allergies or contraindications to immunizations that have been developed by CDC and our standard and could be implemented and could tag that refusal data set.

Steven Stack – St. Joseph Hospital East – Chair, ER Dept
Tim Elwell?

Tim Elwell – Misys Open Source Solutions – Vice President
Yes. I just want to start with, Sarah. I just am gratified that you're using Open Source technologies. It's nice to hear that they're working in your environment. I actually tried to download; I couldn't find the code, so perhaps you could tell me where to find it.

There were a couple of questions that I had for Scott in your testimony that perhaps you could explain. I found the testimony to be enlightening. I enjoyed reading it. There was one piece, however, under the HIE implementation that says, "Given the scope, CHW agrees HIE implementation should have national focus, including adoption of Internet based standards that will enable exchange, as well as the promotion of distributed network architecture for data sharing." I'm right there.

Then you conclude and you said, "And acknowledgement that a business model for exchange should not be driven by commercial gain." That, against the backdrop; and that's on page four of seven under HIE implementation; of economic impacts associated with the PCAST Report are just a curious add. I just would like to understand why that was put in there.

Scott Whyte – Catholic Healthcare West – Vice President, Clinical Systems
Let me make sure I follow the context here. So maybe I can share some information or some context around this. CHW is a non-profit and although we, of course, have for profit partners, many of our vendor partners are for profit and so we're fully supportive and want to make sure that they are successful and profitable. I guess it's more than an HIO necessarily is not intended to be a for profit entity and it is for the public good in our opinion. We do have for profit partners and we have one of, in fact, the greatest, I would say, drivers that we have seen to date of health information exchange adoption has been a clinical integration or ACO-like pilot. So in that sense you could argue that there was a significant quality driver, but also financial cost of healthcare savings, which I don't want to say that's a commercial gain. But the parties of this clinical integration initiative were driven to improve quality, but all the while, save costs that would be returned to effectively the pension group, the patients. So I think I don't want to say that excluding commercial gains doesn't mean that we take away a financial focus, because much of the effort here within CHW, we do believe that access to patient care is important, as is quality. We cannot have expanded access to care unless we provide that care more cost effectively. I hope that's helpful.

Tim Elwell – Misys Open Source Solutions – Vice President
Yes it was. I just wanted to make sure that the sustainability component isn't lost. Second, there was a question or a comment in here that you believe the PCAST Report suggestions with ... will solve problems arising from the patient matching by use of multi factors is naïve. If that's the case, would you suggest some other alternative? Are you suggesting a patient identifier or some other solution here?

Scott Whyte – Catholic Healthcare West – Vice President, Clinical Systems
I think patient matching is a conundrum and I was here in December testifying on this very topic. I regret that I had more concerns and expressed more of the challenges than I did in terms of prescriptions for how to improve it. So I think it is a challenge that we, as an industry, absolutely need to focus on. I don't have a magic bullet. I know there are elements there of sophisticated matching algorithms that can help, but I'm sorry that I don't have the best way to recommend today.

John Mattison – Kaiser Permanente – Chief Medical Information Officer
I think there may be sort of a compromise alternative that's getting tossed around by quite a few folks right now. That is that given the challenges around the patient matching algorithms and sensitivity and specificity and the risks of erring on either side, not getting the information you need or getting the wrong information and putting it in the wrong chart and given that politically it's untenable to have a mandatory identifier. What are the prospects for offering to those patients who have an opt-in process for other reasons to opt-in to a voluntary identifier for quality treatment term, like a VIQ (Voluntary Identifier for Quality)? So it would not be mandatory. People could realize the benefits of having that precision in matching and coordinating their records as they choose within their consent and authorization, but having the existing mechanisms be a fallback for those who opt not to have a voluntary identifier for quality.

I'm sorry. One other comment related to that is I did want to emphasize the importance of the human element. Again, this patient matching issue is often times when the patient is presenting to a registrar. So if that person has to make wise decisions that means there has to be thorough training, follow-up to that training, auditing and then all of that can be supported by tools, but it still is going to rely upon a human and the policies and the workflow and training around that human.

Steven Stack – St. Joseph Hospital East – Chair, ER Dept
John Halamka?

John Halamka – Harvard Medical School – Chief Information Officer
Forgetting that you are the provider and the hospital panel and so much of what you've said is just all of the challenges that you face, I mean you've got meaningful use one, two and three. You've got ICD-10. You've got 5010. It just seems to be never ending. We need practical solutions and I just want to highlight to the group during lunch we were given some extra testimony and John Mattison has written this very thoughtful piece on how to support consumer choice, privacy issues and PHR redaction. We actually solved the problem that I posed this morning, which is great.

He says one of the challenges we all face is that data that we all collect, some of it's structured and some of it's unstructured, the structured data we can probably filter. It's reasonable. There are LOINC codes, SNOMED codes, RxNORM codes, etc. It's the natural language processing of the unstructured text that's so hard. The example that I gave this morning; and I could even make it a bit more flowery; is redact all of my HIV status, my STD history, my mental health history, my substance abuse history, which we can quite well do on problems and meds and allergies and other structures. But if a note had been written I hope that penicillin is making your rash better and that your sadness is going away as you and your partner go on vacation—right? Okay. I've just given you a couple of sentences that have zero from a natural language processing standpoint that would be redactable, but all of us could probably conclude some things about those sentences.

So here's what he proposes: Three levels of consent. I, the patient, consent to have everything shared for quality of care. I, the patient, propose structured data only be exchanged and rules be applied to structured data where possible or I don't want any data exchanged. I like that unless I redact it in my PHR. Okay. Sure. That is the idea that as we are looking for practical, incremental solutions we can phase in today and if I explain to a patient I absolutely will adhere to what you have suggested where the data is structured it's an interesting concept. Of course, there are a dozen cards that just went up, but nonetheless, I applaud your practicality and your proposal.

Steven Stack – St. Joseph Hospital East – Chair, ER Dept
Deven got so energetic there just for a second. You were at the bottom of four more people, but since I think it's to the point, maybe we'll go to you.

Deven McGraw – Center for Democracy & Technology – Director
It will be really quick. Actually, Sarah should answer this. How many of your patients could answer a question about whether it would be okay for them to have their structured data matched or not matched? You guys are living in rarified air.

Sarah Chouinard – Primary Care Systems, Inc. – Medical Director
Assumed a hypothetical question. So really and truly a little bit off subject, but I'm sitting here and looking around this room and thinking you guys should come to see what I do. That's what I'm sitting here thinking and not only what I do, because there are federal institutions, right? Terry and I have essentially the same electronic health record. She's talking about tagging of data elements and how she'd be able to go through and, via looking at a hemoglobin A1C, figure out who's an undiagnosed diabetic. Well, you know what? I can, because I work at a community health center and I've been given the luxury of being able to do a similar function. If I was in a private practice, how in the world am I going to see patients? How am I going to see patients? How am I going to wake up in the morning and go and see the people that need to be seen and then think about the population that I serve and whether or not there are hemoglobin A1Cs out there that are undiagnosed diabetics? When? What hour? Lunch?

I mean it's very unrealistic to think that these high level, data collection analysis and then most importantly, reacting to the data. I've got a guy, a private doc, who I consider one of my heroes, who is using an EHR and he's now collecting data. He's able to say to me, "Do you know what? X percent of my hemoglobin A1Cs are greater than nine." I said, "Cool. Now what?"

"I don't know," is his answer. Right? I know why he doesn't know. Because when? Again, he has now figured out how to make his business run and now he's supposed to take some time out of that business to figure out do I hire now an outreach coordinator and she's supposed to call him? Do I get an educator, who does care coordination? Is that what I'm supposed to do? Do I call you guys? The reason this came up is we were in a meeting about forming an ACO, but nonetheless, it is very tough. I mean the question started with Deven asking a question about would my patients understand structured data, what that means. No and half of the physicians would.

John Mattison – Kaiser Permanente – Chief Medical Information Officer
Lee Tien spoke to that in an earlier panel and Mark Rothstein and Lee and I had a sidebar discussion at lunch. The truth of the matter is that as sexy as the technology and the policy and all of the stuff is stimulating to talk about, the educational deficit of providers and of consumers as to what kinds of opportunities we're debating here on their behalf is huge. I think a lot of what's required for this; and Mark particularly highlighted this; to advance this whole implementation, let alone discussion, is a significant campaign to educate both provider and consumers about what options and alternatives really mean. So I accept Deven's challenge to my simple, pragmatic proposal completely, but I would say the answer is a significant amount of public education, including providers.

Kevin Larson – Hennepin Co. Medical Center – Associate Medical Director, Informatics & CMIO

Let me propose another solution. Sometimes we use, in our technology implementation what I call the Keebler Elves' Model. That's when people think everything is technologic, but there are actually human beings underneath that are doing some things that we can't get computers to do. That's essentially what we do in our exchanges right now through Care Everywhere.

When I ask patients, 99% of them are expecting that I've already been doing this exchange. They think that because we're electronic that's the reason we're electronic; we're exchanging. There is some small proportion of patients that have really legitimate concerns that we need to protect, for those patients we do a human-to-human exchange. So we don't do anything automatically for those patients. We instead have a human being review their record, make sure that we are meeting the patient's wishes and counseling the patient appropriately and then sending that record along. We can scale that because 99% of the patients don't want that. They expect that I'm sending things electronically, so sometimes we make this too difficult, I think, when what we need is an adaptive solution with a set of Keebler Elves.

Terry Cullen – Indian Health Service – Chief Information Officer
I just want to comment though because in my communities that I service nowhere near 99% want their data sent. Nobody wants their data sent. So I think there really is this continuum and the continuum does require what we've been talking about, not only patient activation, but provider activation and the ability for the provider to engage. I think what Sarah said is really true; that there is a time and a fiscal constraint on providers that we need to be attentive to. I work in an integrated health system. It's a little less for me, but Sarah gets hit with it every day.

Sarah Chouinard – Primary Care Systems, Inc. – Medical Director
That's why in my three-minute discussion I mentioned that the reimbursement model needs to change because, again, I don't think it's a lack of interest, a lack of willingness, a desire to see 30 patients in a given day. I think what it has to do with is right now I am being paid to see patients face-to-face in the office, behind a closed door and I have a set of codes that I can use to do so. Everything else is gravy.

So if we can change the way that we get paid, because now all of the quality work that we do, it's just because I personally, Sarah, am doing it really and truly. Physician report cards, do they matter? Just to me and to them, but I mean no one is paying us. There is no incentive. There is no disincentive. There is no suspension of vacation. There are no all sorts of other things that swim around in my head and so doing that stuff is a luxury right now and so it has to become that we make it that it's as mandatory as laying a stethoscope on a chest.

Steven Stack – St. Joseph Hospital East – Chair, ER Dept
As I transition, David, you're coming up next here. I took care of my last patient at 7:00 a.m. yesterday morning after working a string of night shifts. We had a pharmacy resident rotate through and I'm just saying this to punctuate the front-line perspective. About five days into her rotation, we had to have a sit down with her supervisor because she was driving all of our doctors crazy and we were driving her crazy, because she was looking at every patient from the lens of a pharmacist. Did you know this person is on these two medicines and they probably shouldn't be? My doctors were saying, "I don't care. They're here for an ankle sprang. That's someone else's problem."

Sarah Chouinard – Primary Care Systems, Inc. – Medical Director
Right.

Steven Stack – St. Joseph Hospital East – Chair, ER Dept
I know it's uncomfortable and it makes people squirm when we talk about not every doctor is going to do full med rec at every visit and not every doctor is going to review a full, comprehensive list at every visit, but the press and the volume of patients who need care demand that there is a place for problem focused visits that don't go into all of these other things. I don't think that the meaningful use, as we're envisioning, necessarily captures that reality. I think Sarah and others are sharing that. I hope the

passion clearly comes through on the point and it requires other sorts of reform beyond just the technology.

David?

M
Could I add one thing to that? Someone earlier this morning compared the privacy discussions with that of advanced directives and I think to Sarah's point, the value of having an advanced directive discussion with a patient today is enormous. It's enormous to the patient. It's enormous to the physician. It's enormous to the healthcare organization and yet, because of the pressure that all physicians are under for time right now, trying to motivate a group of physicians to get advanced directives in the chart registered and to help the patient think through those options today is a real problem. So given that that's a problem because of the time pressures that Sarah mentioned, imagine how secondary a discussion around somebody's privacy issues becomes.

Sarah Chouinard – Primary Care Systems, Inc. – Medical Director
But I will say this: I mean it's not all negative. I mean meaningful use has been great for improving our business in many ways. In many ways, it's made it much more cumbersome, but something as simple as can you give a visit summary within 72 hours of seeing the patient; could; never have—right? So now there's a place in our electronic health record that as long as I'm putting in the purpose of the patient's visit that day and putting in some of their basic information—I'm not talking about writing the note. I'm not talking about the long version of what happened, but when they leave the office now they get a piece of paper, nothing fancy, just a piece of paper. It says, "You have strep pharyngitis. No, you don't have the flu." Right? Something as simple as that and, "The antibiotic that we think you should take is," or, "We think you should use symptomatic measures," or whatever.

I mean, a la, my father three days ago came home from the dermatologist and I said, "So what is that?" He said, "I don't know." I said, "Well, what did he say?" "I don't know." Bright guy. Really bright guy. Amazing to me. So again, it's because of meaningful use that we're doing that, that we're handing out that piece of paper. We should have done that a long time ago. It didn't cost us anything. It improves our business and guess what? A lot less phone calls from the wife who says, "He doesn't know what it was. Could you tell us?" Right? So it helps. It does help. So I mean there is a balance there between what is impossible to do in a given day and what has improved as a result, so I do appreciate it.

Steven Stack – St. Joseph Hospital East – Chair, ER Dept
And as I transition, I assume we're all proponents for this.

Sarah Chouinard – Primary Care Systems, Inc. – Medical Director
Absolutely.

Steven Stack – St. Joseph Hospital East – Chair, ER Dept
We just want to make it work rationally and well.

Sarah Chouinard – Primary Care Systems, Inc. – Medical Director
Right.

Steven Stack – St. Joseph Hospital East – Chair, ER Dept
David?

David McCallie – Cerner Corporation – Vice President of Medical Informatics
I hate to shift us back to PCAST questions from this much more interesting discussion about the difficulties of practice, which we really need to hear about, but I have a question that is based on Bill Stead's hypothesis of sort of a thought experiment. Assume that it was feasible to do what PCAST said and that ICD-10 and 5010 and the other things were either settled or out of the way. One of the things

that's in the PCAST Report that hasn't gotten as much attention today as I thought it might is two things: One is that it's a shift towards aggregation models that are not based primarily on regional aggregation. It could conceivably be national or it could be multi-regional. It could be health-bank like where a consumer chooses who their aggregator is. The second is that the consumer has the choice as to what's shown back to the people that accessed that record, so my question is would your institutions have any difficulty in participating in an arrangement where the sharing isn't regional, so it may be to an entity that is not known to you personally. It may not be your local based HIE or regional HIE. So that's question one: Would you have any difficulty participating in the upload, if you would, of the data, allowing the indexing to occur?

The second question is would you trust or under what circumstances would you trust accessing that data, knowing that the patient has some control over what you see, whether it's detailed redaction or structured data only or whatever? That's a broad question.

John Mattison – Kaiser Permanente – Chief Medical Information Officer
I personally, as a primary care provider, would love that. My fear would be how much money we'd have to spend in lawyers. So for our Care Everywhere solution I tell people it was a month of IT and a year's worth of lawyering and so the more of these kinds of exchanges we have, the more we invest in the legal and arrangements and the more they cross state lines the more challenging all of that gets. So I fully believe in the idea and really want, in principle, to make it happen. What I would ask for is that we minimize the numbers of those transactions, the number of possible combinations and permutations, because in the current framework each and every one of those combinations and permutations is a new, negotiated, lawyer exchange for us.

Sarah Chouinard – Primary Care Systems, Inc. – Medical Director
For me, the second part of that question is some information is better than no information. So I think the key is if information can be selective or partially protected, as long as I know that, I mean I worked in an emergency room and the number of people that we gave medicines to having no idea what their other medicines were constantly, right? I mean you do it today. It's one of those things that I'd take anything. Give me a few diagnoses. That's better than not knowing any at all, but I think the key there is knowing what you're looking at. Are you looking at 50% of the information or not?

M
Right.

Terry Cullen – Indian Health Service – Chief Information Officer
I think the other thing is if you want to look at low hanging fruit, especially because of the state issues, which is that huge matrix that none of us want to touch, you go into the public health arena where there is some ability and consistency across the states. There is also a huge benefit to society, as well as populations, as well as individuals to know what's going on in different states. So I think the buy-in from an approach like that, I was just in New York; I'm sick now. Is there H1N1 in New York? Can you check on the line and let me know? So I think that there are ways to approach this where you can aggregate beyond your region and see tremendous benefit both, to the patient, to the provider and to the United States.

Scott Whyte – Catholic Healthcare West – Vice President, Clinical Systems
The way that I would approach the question is with the observation that you get what you incentivize. So if the business model of this HIO had any opportunity to monetize the data I would stay as far away from it as I possibly could, because that's such a corrupting influence in the data. The ability to monetize data with pharmas in particular is huge and given my earlier comments about the difficulty in deidentification, I think monetization in a world where you can't deidentify is really a problem.

So I would look for two things in the incentive model, in the business model of an HIO that would help lead us to success. One is can they be as secure or more secure than anyone else? The second is are

they rewarded in some way for representing consumer choice? If it met those two criteria I'd be interested. If it didn't I wouldn't. If they monetize data, I wouldn't touch them with a ten-foot pole.

John Mattison – Kaiser Permanente – Chief Medical Information Officer
Related to the question about should it be regional or a portion of the country, I think the answer could be it could be phased. I would say initially there's a big demand or it would be better to do it regionally or locally. One of the reasons would be, of course, most of the patient care takes place locally and so the biggest value is right there of having just your providers within your community be able to share clinical information with each other. The state laws we've already covered are important.

Then, also related to data quality, for patient matching for instance, there are main differences based upon ethnic groups and different issues where today typically we tune our matching algorithms specifically for that population. Similarly, there are data quality issues or there are clinical conditions that are more prevalent amongst one community or another. Where there are anomalies, where you see issues with data quality it is much easier to bring those issues to the front line where they're often created if you're close to that front lien and you understand the local patterns of data quality problems.

Steven Stack – St. Joseph Hospital East – Chair, ER Dept
I've got 6 people, 12 minutes. You all do the math. So if we can do this kind of rapid fire a little bit now? Hunt Blair?

Hunt Blair – OVHA – Deputy Director
First of all, thank you, all. This has been extremely informative. I don't think, actually, that we departed too far from PCAST, because I think the whole point of this is not the technology, but what we're doing with the technology, right? Absolutely payment reform. I guess that's why I'm on this panel workgroup, because I'm the Director of Payment reform and Health Reform in Vermont.

Sarah, you spoke very eloquently about patients driving change and about using PHRs. You also said you got this question of why do I want to use it. So I'm interested in, first of all, what is it you say that changes that. Secondly, do you think that their engagement with HIT can help with this whole question of their position on secondary use?

Sarah Chouinard – Primary Care Systems, Inc. – Medical Director
Well, two things: Every time I speak anywhere I tell everybody, so I'll say it here today too, that it should bother you if there is a manila envelope with your health record in it locked in a basement. If that's the record that exists on you and your healthcare, which is happening a lot, more than not, that should be worrisome. So I tell patients that.

Then, as far as getting them engaged in caring in the process, I explain very sophomorically, "Here is the thing. The only way that I've been able to get a handle on what you need is by having a computer help me do it." I literally make it that simple. I say, "If your chart is stuck in the rack what can I possibly do except walk by it every day? If you happen to show up I might think about it." That's the way that I used to practice medicine. That's honest. So I tell people that by being a part of this larger process that we're going to be paying more attention to you when you don't happen to be sitting here in my office and you're going about your daily life, ignoring your chronic condition that's not bothering you today.

The interesting part of that is we pat ourselves on the back and think we're these quality do-gooders and occasionally we'll call people up and say, "Hello, Mrs. Smith," first of all, figuring out if we're allowed to call her, right, as a privacy issue. Will she let us make a telephone call to her house or do we need to contact her by letter and if so, can we have it on letterhead because she doesn't even want anybody in her house knowing that she comes to our clinic? I'm exhausted too. So we call her and we say, "Mrs. Smith, you're on our list and you need a mammogram," and a ferocious response of, "If I wanted a mammogram I would have had one. Leave me alone. Please don't call my house again." I mean I was shocked. Here I was, I was thinking you're supposed to say thank you, right? You're supposed to appreciate me.

So her point is well taken, but that's the exception to the rule, but it's the squeaky wheel gets the grease concept, right? So those patients that are out saying in the community, "Don't go to that health clinic. They'll call you." Right? So there's always something I guess is the answer. So all we do is we have all over our waiting rooms, all over in every site and we're pretty wide spread what the benefits are. It's just simply a matter of we can't possibly think about you unless we have the help of a computer to do so and we can't know what your health status is and you're sort of, year-at-a-glance, that's the concept that we use. We don't expect that you know everything. We do, but we're not always thinking about it.

So then the PHR pitch is be your own advocate. I tell people if you were to see me every three or four months, you basically spend an hour and a half with me annually, that also should be about you're the doctor, whatever you say. Really? An hour and a half annually and it's up to me? So it's that patient engagement from a self-management standpoint, which is harder to do, but it seems to be a pretty easy sell on why they should want it and then the privacy concerns, so far so good, because we're not exchanging. We're just allowing people to have access on their own.

Steven Stack – St. Joseph Hospital East – Chair, ER Dept
Carl?

Carl Dvorak – Epic Systems – EVP
I'm an engineer and not a physician, so I come from more of a patient perspective on some of this than as an insider. Listening to the panel I was trying to understand how much you think patients care whether they have digital health information exchange. I must say some of the discussion made me feel like you don't think they think it's important and it's a hassle for you and it's not worth it. Theresa quoted a figure that 99% of people don't ask for their records at all, if I understood that correctly, so I'm just wondering where you come down on that.

Sarah Chouinard – Primary Care Systems, Inc. – Medical Director
Just real quick, I mean I think just the opposite is true. It's just that they don't understand it. I don't think that they're saying I get it and I don't want it. I think it's the opposite of that. It's just not understanding. I guess that was the point I tried to make about saying they understand what they should get out of a doctor's visit, but they don't understand what the benefit of technology is. So I think that we have to do while we're attempting to do these things by 2013, 2015, whatever, what the lowest hanging fruit is is get people to want it. Get people to demand it. Meaningful use has done a good job getting providers to demand it, sort of. But I mean it's a good step in that right direction. So what are we doing on the patient side? How are we getting patients to care and get interested?

So I think, Terry, I'm going to speak for you: The 99% is not that they don't want it. It's just that they don't ask for it. Yes?

John Mattison – Kaiser Permanente – Chief Medical Information Officer
Let me throw out a figure of 40%; 40% was the response rate we got when we sent a single mailing out to veterans in San Diego, who we identified as having received care, both at a veterans facility and at a Kaiser Permanente facility. So a 40% voluntary response with virtually no education other than the consent letter that was sent out. Since then I've actually had patients call me on my cell phone, having looked up my cell phone number on the Web, having read the newspaper article that I was leading the project, saying, "How can I opt-in? I didn't make it in the first cut. I want to opt-in now."

Let me just give one short vignette of how it works. One of our very first patients, who had been seen at both institutions, back and forth, showed up at a Kaiser Permanente facility and the intake nurse said, "And what are your medications? What are your allergies? What are your problems?" An update. He hadn't seen his family practice doctor there for quite a while. Proceeded to evaluate the patient, whose blood pressure was out of control, whose cholesterol was very much not in control and that physician very

likely would have prescribed in a class of medications for the cholesterol and the hypertension a drug that had been noted to cause a life threatening allergy within the last six months in the VA.

When the physician pushed the button and send, "Send me the C-32 from the Veteran's Administration," and they instantly got the list of allergies the physician was able to say, "Is it true you're allergic to an ace-inhibitor? Is it true you're allergic to a statin? Is it true that you had these life threatening reactions?" The patient said yes. That was one of our very first patients. So I think the story will be told, the education will result from real-life experience, but that doesn't obviate our obligation to initiate a much more proactive educational campaign about what the opportunity is for consumers.

Kevin Larson – Hennepin Co. Medical Center – Associate Medical Director, Informatics & CMIO
I think there's kind of a consumer tipping point in our market with heavy penetration. Consumers are demanding it. When we actually asked patients about personal health records, which we do now at nearly every encounter, about 60% of them say they want them, so when it's present and people trust it they want it.

Terry Cullen – Indian Health Service – Chief Information Officer
I just want to say in my communities we only have 22% Internet penetration, so with only 22% Internet penetration you've got a lot to start with that aren't going to want it. But the one other thing, and this is another vignette, data just came out this week saying if you have more than 10% genomic heritage that's Native American in the U.S. your response rate to ALL will be different than standard chemo if you need to have an additional treatment added and then you'll have similar response rates. That information has, in fact, penetrated our communities with people saying, "Are you going to make sure you have that information so it can change what I do?" It's really about benefit.

Steven Stack – St. Joseph Hospital East – Chair, ER Dept
Right. With my apologies to the others, I think Walter is going to get the last question. So maybe if you can single someone out and pick one person so I have a minute to close?

Walter Suarez – Institute HIPAA/HIT Education & Research – Pres. & CEO
My question is about something that Marc Overhage talked about earlier. It is the concept of trying to normalize the data at an early stage. I mean I'm a person that has been involved in standards for many, many years. I'm all about standards. The good thing about standards is there are many standards. The challenge, of course, is the more you provide optionalities and the more you provide alternatives and the more you provide the ability for a standard to have optionalities the more you need things like mapping and translation and mechanisms to, when a data is exchanged, have to reconfigure or translate or create some way of mapping that. So the question, since you are represented providers and hospitals that use these systems that exchange data, should we try to move in the direction of expecting that the systems that are used are going to natively be able to use the standards in the most precise way? Taking away a lot of the optionality and a lot of the need to do mapping in the outset as the data goes out so that in the future we can see things like what has really been proposed in meaningful use two? Things like the green button; that I press a button and a message gets generated and gets sent out?

Kevin Larson – Hennepin Co. Medical Center – Associate Medical Director, Informatics & CMIO
Yes. I would say the answer is yes. Most of us don't have one system. We have 100 systems internally. That doesn't just help us interoperate with other places. It helps us interoperate within our own place.

John Mattison – Kaiser Permanente – Chief Medical Information Officer
The short, technical answer is that every transformation and mapping you do results in semantic degradation and so the more hops you have in that process the more ... from the source, the less reliable and accurate and precise the information is, so the closer you put the normalization to source the better. That being said, practically speaking, to Kevin's point, there's a lot of work to do to get it there.

Terry Cullen – Indian Health Service – Chief Information Officer

I would argue that there's a reason why diabetes mellitus is not otherwise specified as a very common code used by providers. So if you want that granularity you've got to figure out who's going to do it.

Steven Stack – St. Joseph Hospital East – Chair, ER Dept
Well, let me thank our panel. I hope everyone else found this as exciting as I did. I'm going to do a quick wrap here. I guess there is some concern about the timeline being ambitious, but I think we all know that. The privacy tags have potential benefit, but also some potential implications that you all highlighted that we need to consider. I think the idea of a PHR being a way to propagate or propel people's uptake is interesting and a little novel compared to what I had heard before, so that's worth further thought. The middleware is a concept. It could help bridge, but it's not without it's down sides. Patient matching: We didn't dwell on this, but it's a conundrum apparently from your level that you would have, probably, I think expounded on that more had we asked more questions about it. There were many, many other interesting points.

If I could offer one other side point, not specifically to the PCAST Report, which is when we got off on that tangent, talking about the clinical care. It's difficult, but I think if we could make some more space in some of our deliberations for that, because I think there are some insights from the docs and the nurses and the other allied health professionals, who are delivering this, because in many ways we're as naïve as the patients for this technology. It's a tool and we need it to work and we need it to work when we need it to work. That's about as deep as our understanding is going to get a lot of times. So you all do not typify the rank and file doc, who doesn't understand this stuff, but thank you for all of your insights.

Paul Egerman – Software Entrepreneur
That was extremely insightful. Our next panel is panel number five. It's the Technical Panel and the moderator is John Halamka. If we could ask the technical people to be seated? ... that panel.

John Halamka – Harvard Medical School – Chief Information Officer
So we heard this morning that, of course, once all of the hard policy work is decided that there are no technical barriers that the panel in front of us cannot overcome, so I'd like to introduce to you four magicians. We're going to hear today from technologists and organizations large and small in proprietary and homegrown and Open Source. We have Michael Stearns from e-MDs, a small vendor. We have Hans Buitendijk from Siemens, a large vendor. We have John Melski from Marshfield Clinic with a home-built electronic health record; and Edmund Billings from Medsphere, an Open Source support company using the Vista Source code base.

With that, I would like to begin with Michael Stearns. Talk to us about some of the technical aspects of implementing the PCAST Report.

Michael Stearns – e-MDs – President & CEO
Thank you very much. On behalf of the HIMSS Electronic Health Record Association, the EHRA, we deeply appreciate being given an opportunity to testify before the PCAST Workgroup. My name is Michael Stearns. My position, I'm the President and CEO of e-MDs medium sized EHR vendor, small to medium, somewhere in there. E-MD is a member of the HIMSS EHR Alliance, a subsidiary of HIMSS. I'd like to provide you with an overview of our members' feedback on the PCAST Report.

We appreciate PCAST's recognition of the importance of healthcare data and the essential requirements to share that data across time and locations for individuals and populations. We agree with PCAST that the exchange of healthcare data should be at a more robust level in future stages of meaningful compared to stage one and the currently proposed criteria for stage two. We also agree with the need to focus on meta-tagging within XML in a way that creates reusable data elements for use in clinical care, population health, cost effective healthcare and clinical research. In addition, we agree that a focus on the need for privacy protection ... patients is a very high priority.

However, we feel that the focus in the PCAST Report for individual data elements separated from specific documents and records would be problematic and has potential to remove the critical context needed for patient care. We are interested, however, in exploring how PCAST tends to manage this process in greater detail as a process separating data from critical, clinical and patient context and then reassembling it later for later use has potential to jeopardize patient safety. That's our concern.

We are concerned that granular clinical data summaries divorced from their source documents would not result in accurate or complete clinical information. For example, it's unclear to me how the PCAST approach would identify, store and reassemble commonly used, but complex clinical expressions. For example, under assessment you might see, "Sudden onset of severe headaches. Bouts of ... hemorrhage based on prior history of similar headaches," which wouldn't be that uncommon. So how would we handle something like that? We feel instead of pursuing this approach ONC and other HIT stakeholders should focus on data elements within contextual documents rather than isolated data elements focused, as consistent with and built on stage one meaningful use.

Metadata tagging, essential to sharing health information, the key standards implementation specifications, test tools, Open Source and products already exist and support more robust, bi-directional HIE. Interlinked standards, such as consolidated CDA templates, XDS, metadata tagging exchange, XCA, already provide a universal exchange language, arguably, for healthcare information called for by PCAST. They do so, however, in a manner to balance innovation, incremental development and deployment and deep domain knowledge. ONC should, building on work done in the NW-HIN Connect and Exchange projects, implement bi-directional, publish/query based approach to HIE and stage two and stage three meaningful use utilizing proven approaches, those demonstrated by Integrating the Healthcare Enterprise for files ... XCA and XDS.

There has been extensive debate over the advantage and disadvantage of granular segmentation. We've heard that earlier today for much of the day. We also agree that a great deal of testing needs to be done if we're going to implement anything in the privacy domain. At its highest level, PCAST seeks to create an environment that breaks down barriers to the exchange of health information. We feel this objective can readily be met by the coordinated effort that involves multiple stakeholders, including ONC, CMS and other federal, state and local government entities, standards organizations, provider organizations, consumer organizations and the HIT industry. The focus on metadata tagging and XML is already supported by the ONC via standards in our ... framework initiatives. ONC is close to completing this task with the CDA consolidation and transfer-of-care initiatives that build upon HITSP/C83 and leverage the support of HL-7 and IHE. These efforts should be supported and accelerated.

For the majority of EHR vendors the cost associated with converting to the universal exchange language described within PCAST, while simultaneously providing for the clients while they obtain meaningful use and transition to ICD-10-CM, X12, HIPAA 5010 and other requirements would be very challenging.

With regards to standards, the primary cost is not about the engineering resource. It is related to the time and uncertainty associated with new standards development. Developing a new standard when several competing standards are already in existence may not be in the greatest interest of healthcare. Another consideration is how data should be shared with other countries, which was not fully addressed in PCAST.

In summary, there is no need to rip and replace existing efforts accomplished in HIT. These programs have wide stakeholder input and support and are approaching a point where broad interoperability can be achieved. We need to consider the impact on patient safety of any proposed changes that affect how we share information between healthcare providers.

John Halamka – Harvard Medical School – Chief Information Officer

Thank you very much. Believe it or not, you did do it in the five minutes allotted. I had hand signals from the back. So you have five minutes, even though the timer had originally said three. Hans, please continue.

Hans Buitendijk – Siemens Medical Solutions – Senior Product Manager, Healthcare IT Division
I'd like to thank the Chair and the Workgroup for the opportunity to testify on behalf of Siemens. Siemens has been a leader in advocacy for and implementations of standards in healthcare across the full spectrum of clinical and financial domains since the early days of healthcare IT. We have been very active and supportive of standardization efforts to improve information exchange, both within provider organizations, as well as across provider and payer organizations. We have found that establishing standards to support these information exchanges are iterative, built on what works and take time.

The PCAST Report describes an interesting and expanded view on facilitating cross provider communication. The idea that cross provider communication can be enhanced by expanding dynamic pool communication capabilities is compelling. Tagging data sets to enable casting of wider ... finding new patterns and raising the level of knowledge for a single patient or across a population is compelling as well. However, we do not agree with the notions that tagging data, introduction of XML and dynamic pool communications are the sole keys to successful cross provider communications.

Their active push communication, where we are sending information to specific recipients with well-defined and agreed to content will remain a critical component of any provider to provider, provider to patient and patient to provider workflow support within and across provider organizations. Instead, we see five critical success factors. We need to agree on reasonable privacy and security guidelines as data freely flows and as patients need to be able to manage their privacy. To correlate data related to the same patient we need to agree on how to support that, a unique patient identifier or probabilistic logic that achieves just about the same. Is probably the same good enough?

How do we address the needs of the patients and clinicians by observing appropriate context? Many examples have already been shared today of why preserving context is critical. Today documents do provide such ability, but other data sets may be appropriate as well. Significant data is still encapsulated in unstructured, free-text notes. How do we unlock that? What data capture technologies and process enhancements are needed to unlock this data? Natural language process and technologies are not far enough along to reliably perform that task. Capturing sufficiently structured data that fits into a clinician's workflow needs to further evolve as well and the costs will not be low. Current coding efforts to just support a limited purpose, ICD-9, CPT-4, is already very costly and not done by the clinician.

How do we incorporate new-found data from dynamic queries back into a clinician's workflow, assuming appropriate privacy and security policies are in place? Incorporating this data into secondary data use project is one thing. Incorporating this data into direct operational support is quite another where this morning Marc Overhage's three-second rule is a critical consideration.

Last, but not least, we need to agree to the vocabulary necessary to make the data useful and meaningful, as well as the metadata definitions and the level of granularity that are useful throughout the clinical workflow and research. Rather than building from scratch, we need to build on what we have and continue on the path of expanding the information exchange for new use cases, while solidifying the necessary vocabulary. Consider adding metadata to documents to reach into the finer grain data available within maintaining and while maintaining context. Explore complementary and/or replacement data sets that are not based on a document ....

We know that reaching agreement on vocabulary within one provider organization is already a challenge. Harmonizing vocabularies and common data structures across providers compounds this challenge. Addressing these fundamental questions takes time and the answers have to evolve through experience. Certainly, they cannot be answered sufficiently and have solutions implemented and rolled out to the provider community by 2013 or 2015 and switching directions midstream rather than staying on coarse

long enough to see the benefits would be disruptive. But steps can be taken to build upon the current state and make incremental progress. We suggest to take advantage of the newly defined S&I framework, which promotes open, transparent participation from a wide range of stakeholders and focuses on creating demonstrable pilots and reference implementation code that is tested in real life settings.

Specific topics to tackle in context of the critical success factors identified and building on what we have could be identify further metadata tagging on documents, identify alternative data sets, varying degrees of granularity, explore privacy and security methods, establish patient identification approach, deliver a pilot that can demonstrate a potential, while clarifying the next steps.

With this, I would like to finish my remarks to stay within the five minutes.

John Halamka – Harvard Medical School – Chief Information Officer
Four seconds to go. Well done. John Melski?

John Melski – Marshfield Clinic – Medical Director, Clinical Informatics
Hello. I'm going to give you a perspective of someone who is in the trenches. I'm a practicing physician. I have spent the past three decades helping build our homegrown EHR, as you've heard. So I'll try and give you some perspective or at least emphasis; I think most things that need to be said have been said. I'll try not to be redundant with other speakers, but I want to emphasize the work effort that's involved in getting structured data. I am a normalizer. I'm in the trenches providing that structure and there's no doubt that there's work involved there. The value of the data depends upon how much structure there is. As you hear about normalizing that source, I'm the source. So I have to normalize. That means I have to make all of that structure available so that it's highly reusable, not only for decision support, but also for interoperability. That will be your principle cost, because there's a shortage of primary care providers. Many of the patients I see don't have primary care providers. So I take it upon myself to try and enter some of the structured data for some of those things that are beneficial, not only to the patient, but also o so that they can also be picked up for surveillance for other things. So there's a huge cost to that.

My concern with the PCAST conceptualization at this point in terms of tagging security down to the data element level is who is going to provide that work. We've already heard that it's extraordinarily challenging for patients, but I can tell you that it's extraordinarily challenging even for professionals to kind of understand the implications of these things.

One thing I that was alluded to that I'd like to sort of just make a potential note on at this point is if someone restricts their data and harm results is there any thought that there should be a safe harbor for the providers, who acted in good faith, but didn't have the data because the patient withheld it? I think that any part of a patient consent should involve consideration of the consequences and to holding harmless people who act in good faith, who can't do their job if they don't know that a patient is on a certain medication that interacts with another medication.

The other emphasis that I want to place is that there is a presumption that we're much further along with the usefulness of clinical decision support than I personally think we are. There are notable exceptions and I read the papers and I know that there's value and so forth, but there is an assumption that things are much better than they actually are. I think drug-drug interaction is a classic example. The signal to noise ratio, the signal is very low and the noise is very, very high. I have not seen that the marketplace provides solutions. We have a vendor who gives us the names of the medications that we use, but the decision support is very poor and as a consequence you get so many false positive signals that it really is not helpful. So the assumption that everything will be good if we can transmit all of this information is not really validated in the current literature or in personal experience; that we have a long way to go to actually make this data highly useful.

Now, I've dedicated a good part of my life to that vision. I still believe in it, but I also understand the consequences of raising expectations and then not meeting them. So I'm here to kind of bear witness to the fact that there's a lot of work that needs to be done.

Finally, despite all of this, I think that there are certain domains in which we really, really need to get started. We need to stop debating whether we should drive on the right side or the left side of the road. When there are vocabularies that are sufficiently advanced, and I can't say for certain that I know this to be true, but I believe and hope that a standard like RxNORM, it's time to start moving forward. Yes, there will be people who will suffer if that becomes the standard, but we need to do this because that's the way I think the market is going to help with decision support is when I can easily change from one decision support software to another because I am writing all of my electronic prescriptions. Which we did long before there was an incentive to do that, I'm writing that in a standard vocabulary that gives value back. I would encourage consideration of data governance over these lexicons so that stakeholders can be involved and then, of course, LOINC and some of the other vocabularies will follow quickly after that. Thank you.

John Halamka – Harvard Medical School – Chief Information Officer
Thank you. Edmund?

Edmund Billings – Medsphere Systems Corporation – Chief Medical Officer
Thank you. Thank you for allowing me to share my perspectives on the path forward. I will focus on the mainstream hospital market where we live, the 80% or so that have not adopted yet any clinical systems and that have operating margins that range from 2% to negative 5%. If they're going to adopt a universal exchange language it's got to be made relevant to them. It's got to be practical, affordable. The complexity that we're talking about here, the complexity that's outlined in the report needs to be commoditized.

Our experience with the meaningful use has been dramatic. The change for someone who's been working in electronic health records for two decades, the change in the conversation with these customers and these clients is dramatic; the urgency, the interest that now EHR is an imperative; before you talked about benefits. You talked about features. You had to drive to the complexity and you didn't focus on the outcomes or the use. So now the conversation is about the use. It really allows you to align the executives with the IT department with the clinicians. I cannot over emphasize how important that is. It's a fog cutter. They have to organize and understanding meaningful use themselves, so they aligned. They have to have these conversations and they look at why they're doing it versus the technology to get them there. In terms of exchange, connecting to their physicians is a priority. PHRs and connecting to their patients is nowhere in sight. They don't even care about it at this point.

In regards to the universal exchange language, healthcare is collaborative; the information sharing infrastructure must also be collaborative. Sharing, and we want to share potent and, I believe, focused information first in an incremental fashion. This will fuel the network effect. It's going to be valuable to the stakeholders receiving it and we need to focus on the value, not on the science. So I would say proceed incrementally and focus on supporting the continuum of care with a health summary, one page of paper on-line that is potent and valuable to everyone that receives it. Look at the care providers first and the patient first.

I'd use Pareto's Principle, the 80-20 rule, to define the most potent elements within it. Then I'd assure, as you've heard already, that the business models need to be in place. When business models are in place standards will evolve and become practical and usable; otherwise it's all just talk. I'd model on the Internet, but I'd accelerate and commoditize, using Open Source community and platforms. Public domain is nice, but it's a path of engagement with the community. Open Source is collaborative and will drive adoption much faster.

The term Open Source was only mentioned once in the whole PCAST Report. It was related to Vista. It didn't talk about it as a means to get to this result, which is, when you listen to Google's CEO, Eric Schmidt, who is also a PCAST member, he mentioned it five times in a brief comment he made about the report, so it not being in the report is kind of striking to me. He said that using such an Open Source strategy would give programmers the freedom to modify and distribute software is a prove way to fix disparate software architectures. It's the same development that brought us the modern Internet and all other technologies that we use every day. So if we want this used every day we might consider it.

I'm just going to show you a couple of things in terms of the Open Source service business model. This is ARRA dollars for a 200-bed, community, county hospital. You can see that the ARRA dollars for five years; they have a bid Medicaid share; is $7 million. The cost of an Open Source solution, a full EMR, for their organization was $3.9 million. That gave them a savings of $3.2 million. That savings of $3.2 million is being applied for on the ground services for adoption for change management. They don't have the people. Now they can actually hire the people to do the work.

Lastly, I'm just going to quickly show you this is the proprietary versus open choices that they had for doing interoperability. You can see the on the left the proprietary cost was $750,000 versus $144,000. The key there is that the Open Source drives the complexity down. The complex interfaces became intermediates and then became base.

John Halamka – Harvard Medical School – Chief Information Officer

Great. Thank you very much. Clearly, a lot of hard work described by these folks from the technology side. Some common themes. Several of you were concerned about context and whether we should exchange documents or summaries versus atoms, molecules or pieces that may lose some context.

All of you described the issues that you're facing, multiple technical challenges simultaneously. meaningful use one, two and three are creating a sense of urgency about 5010 and ICD-10 and many of the other things on your plate make a change in direction now somewhat challenging. You also talked about vocabularies and how vocabularies would be quite important. Certainly, the Standards Committee has said to ONC that it would be very important to put up an Open Source kind of fashion, a single location of vocabularies and crosswalks necessary to accelerate all aspects of meaningful use stages one, two, and three. So I think that vocabulary theme is one that we're all very familiar and supportive of.

You also mentioned that maybe we're not as far along as we should be or think we are. I think this is sort of an interesting issue. As I reflect on my own implementations of home built systems and people say, "But wait, every hospital in the country has full decision support, has structured documentation, has paperless hospitals," to which I respond a paperless hospital is as likely as a paperless bathroom. But we are getting closer. It is true. I'm in Japan next week. I hear there are paperless bathrooms there.

So the idea that we need to move forward incrementally, that we need to move forward to structured data capture, you also highlighted that structured data has a cost. For every element that you capture a structured fashion takes programming, vocabulary building and physician time, but yet there is great value to be had from that structured data in terms of decision support or downstream analysis.

With that, let me just start off with an interesting question. I actually think there is sort of unanimity about the notion of having documents and context. One of the things that I felt like we've been challenged by as a workgroup, as we talk about PCAST and its focus on data atomic we've been trying to find what an atom is. What is, if we want to take that context that is the document that you all described, and break it into something smaller, assuming there is structure, assuming there is vocabulary, what should that smaller unit be? Because one could define an atom as a field, problem, onset, date. Maybe that's not actually sensible, so maybe an atom is actually an allergy name, an allergy code, an allergy onset data, the severity of allergy, who observed the allergy. Maybe that's an atom or maybe it's the whole allergy list. So as you guys, as technologists, have read through that report and you've all made your comments about context, do you have thoughts on what is an atom?

Hans Buitendijk – Siemens Medical Solutions – Senior Product Manager, Healthcare IT Division
... response first. I think the answer is actually that it lies on a continuum in a way; that for certain purposes that a document is appropriate, for certain purposes a section within a document is appropriate, for certain purposes we may need to go deeper. Even if we need to have the context in order to use data for particular clinical decision support, while we need the context at the individual data level, we need to have agreement on do we maintain a unit of measure as part of the value or as a separate field and those types of conversations. So I think the answer can be at various levels depending on the use case, depending on what we're trying to achieve. The nice part is that by progressing from where we are we have the opportunity to build out, continuously build out vocabulary at those different levels to build and figure out what the right level is going to be over time as opposed to assume that the atomic level is at the detailed value level. Take those steps as opposed to jumping into it with both feet too fast.

John Halamka – Harvard Medical School – Chief Information Officer
....

John Melski – Marshfield Clinic – Medical Director, Clinical Informatics
I think that the level of abstraction is the sort of answer to the question. It's the same atom, if you will, or molecule needs specification to a different level depending upon the use that it's being put to and so some attention to this level of abstraction issue. I think that medications are sort of a classic example. It's that for certain purposes like, for example, specifying that you're allergic to something is very different than saying I need to specify it to prescribe it.

The notion that I need to prescribe it doesn't necessarily mean that it has to be grape or cherry flavored. I can defer that to someone else, presumably, the patient, who has to swallow it. So it's this level of abstraction issue that, to me, is one of the things that you really need to pay attention to because the atom will look different to support different realms.

Clearly, the most troublesome area is the area of diagnosis, because it's so amorphous and so difficult. But even there I think that one way to eat an elephant is, of course, one leg at a time. One way, I think, to start to focus, if the focus were to look at medications as sort of a test case, can we standardize on medication, which I think would be an enormous benefit. Immediately start to open the door. Okay. What about side effects to medications? Well, you need diagnoses to capture those side effects.

Then you need diagnoses for indications for medications. Those would be the two legs of the elephant I would start with in the diagnosis realm to support the ability then to record adverse reactions; not necessarily the unanticipated heart attacks and so forth, but the known, acute skin failure types of things that I deal with in my practice. Then that would be a subset of the diagnosis. That would be supportive of the allergies, which is grossly underestimated and people are very glib about how easy it is to do and just in case those who don't practice medicine, when someone says they're allergic to penicillin there's a 90% chance that they're not. That's the kind of data that we deal with every day, so you really have to kind of understand how fuzzy some of these concepts are. They sound so precise, but they're not actually.

Anyway, that would be a way that I would approach atoms in the diagnostic realm and then the lower hanging fruit, although still complex, medications and laboratory tests.

John Halamka – Harvard Medical School – Chief Information Officer
Very good. Let me actually add to your description of a penicillin allergy. This actually illustrates the challenge that we have of deciding how to codify and structure our data. When I was two years old I had an ear ache. My mother got me some pink medicine that tasted really quite nasty. I developed two spots on my abdomen, so for the rest of my life I was labeled penicillin allergic. However, the way I think of allergies, a set of detailed clinical models looking at the substance; the observer, my mom; the level of certainty, unlikely; the reaction, two spots on my abdomen. So it was probably about five years ago that I was leading a mushroom hunt in Lyme, Connecticut and ten days after I led that mushroom hunt I

developed large, target lesions all over my lower extremities and was diagnosed with Lyme Disease, to which I was given an Amoxicillin tablet, a penicillin. I can tell you after six days on penicillin I can now confirm to you the reaction is severe. It is quite certain and I am very pen-allergic. But unless we define an allergy as all of those things that I said it was, the substance, who observed it, the level of certainty, the kind of reaction, we aren't going to be able to actually interpret the word pen-allergic to mean anything.

So my second question—and then we'll open it up to others, is if we are going to get beyond the level of the document into some atomic level, dependent on the context, do we need to have detailed clinical models? Not to suggest that every EHR has to have the same underlying data structure, but if we were going to exchange the problem list, the medication list and the allergy list do we have to determine what are the subcomponents at a detailed level that are in those kinds of apps?

Michael Stearns – e-MDs – President & CEO
I would agree we have to do both. We have to actually maintain the document; at least for now and then we have to explore how much of that we can do. It really needs to be field tested aggressively. I think that's what the concern was. A member of the member organizations; yes, it's a good theory. It's potentially very valuable. We need data, but there are a lot of concerns about using that data in different contexts. Using it for clinical care is a lot different than using it for research in my opinion. You need clean research data, but obviously, if you're an emergency room doctor, if the information comes across the HIE you see it, you're going to react to it very quickly. You're not going to have time to validate it. So you need to make sure in certain contexts that the data is very clean.

Edmund Billings – Medsphere Systems Corporation – Chief Medical Officer
The only comment I would make is that I think that doing this type of conceptualization about the design would be a lot more focused if we had the use case. If you took those seven or eight use cases in there and we found the one that we thought was the most compelling first use case and then went after these questions, because then you could actually get the context, get the atoms. Get the model for that use case, because in the abstract, you have to consider all aspects or all use case, that's a lot more difficult. It goes back to how we might incrementally design this process. If you're trying to do every one of these with one, if you're trying to get the design, overall architecture right then we'll be talking about this five years from now. You just need to march out and try to do some prototyping in parallel and get the business model developed in parallel so that you can actually drive to real solutions for a specific instance.

Hans Buitendijk – Siemens Medical Solutions – Senior Product Manager, Healthcare IT Division
... the expectation is that on the other side of the communication that the recipient is going to act on the data in a somewhat predictable fashion, consistent with what the data was there should be some agreement on what the model, what the attribute, what the content, what the vocabulary are. If we don't have that then we are only left with the other party interpreting, guessing what it might have been. So going down to that level of definition over time, as we explore the different use cases, not all at once, but as we explore that is a critical element to move in that direction.

John Halamka – Harvard Medical School – Chief Information Officer
Very good. Let us open it up now. Wes, I think you have a comment?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I'm going to start by saying this is going to be one of those questions where the question is maybe longer than the answer. Given there is a lot of room for interpretation of the PCAST Report and we're learning as we go on this committee what represents ideas that are kind of in alignment with the committee and if in a more nuanced understanding they appear more feasible and things like that. One of the issues is the scope of the problem it's trying to solve. There is no doubt that it is trying to solve the problem of more free and widespread, secondary use of data collected in the course of giving care. At a minimum, I don't think anybody would disagree with that. I may be wrong.

It then leads to the question of is it also necessary to do that, to have it also be the way of exchanging information in the course of giving care. That is, is it in some sense a replacement for HL-7 Version 2 or CDA or something like that for all of the things that have already been specified in meaningful use? I honestly don't know what the committee members had in mind there, but it strikes me that some of the questions and some of the difficulties that we're discussing are assuming that that is the intent; that is we're talking about assumptions that this becomes a replacement protocol. It becomes something new. At a minimum we know from the report that the committee members intended there to be a middleware solution, meaning whatever becomes the universal exchange language that that data ought to be produced as well as possible in that format through the use of middleware. So with that as background, let me just ask the question.

If we were to want to start with some specific case where we wanted to be able to generate a format that is more useful for the secondary use of data, at least partially retrievable through middleware. And where we didn't necessarily perceive that we were going to model all of healthcare data to start what would be a good place to start I'm going to ask one follow-up question also.

M
All right.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So that's the question. In other words, work with us here. Say we're not necessarily asking you to change how you store data in your system. We're not asking you to change the model for your system, whether it's report oriented or discreet data oriented. We are asking you to be able to produce data in a new format, unfamiliar to you as of this point that is translatable from your data if you have structured data. I think John has already mentioned pharmacy data a couple of times. Is there a case for being able to use that as a model? Would it bring out difficulties in the commercial coding sources for pharmacy data or difficulties in RxNORM on the other hand? Where would be a good place to start to get a start on this without necessarily saying we're going to change the world before we see what the new world looks like?

Anyone want to go first? John, since you've been kind of valuable on the point of pharmacy I thought you might want to say ...

John Melski – Marshfield Clinic – Medical Director, Clinical Informatics
Yes. To me it seems like it's the lowest hanging fruit. Again, I spend 70% of my time taking care of patients. So I don't want to over represent my sort of deep domain knowledge of whether that's the right choice and what needs to be done and so forth. But it just seems like I'm just expressing this tremendous disappointment to being a bleeding edge, 501(c)(3) developing our own because it was the right thing to do and then not getting the decision support that I really expected when we had all of our medications codified. That's just a tremendous disappointment. I want to spare other people that disappointment. So I'd like to fix that before we try and do everything else because to me it's seriously broken. It's really not providing the value that it was supposed to provide. So I think that's important.

Now, having said that, we are our own middleware company, so the cost of doing that will be ours. So one of the consequences is if you grant me what I wish for it's going to be painful, because we're going to have to support that, but I think in the long-run it's the right thing to do. That's why I turn to the medications as sort of a proof of concept, because it seems like it's the closest to something that everyone would benefit from. There's an enormous need. There's an enormous cost. Poly-pharmacy is a huge issue. Finding out what medications people are on is enormous. It has the same profound privacy issues. Should you really restrict what medications people are on? What are the consequences of that and so forth? I think it's a good place to start, but you've already heard that.

M

You should not believe the witness?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
… not believe the witness, but is there a project that collected enough data that researchers could begin to look at the fairly difficult … problem of effective clinical decision support? Do you think pharmacy data and minimal other data from your system would support that?

John Melski – Marshfield Clinic – Medical Director, Clinical Informatics
Yes I do. I think that there are some other instances that we should mention. I mean even the ability to pass vital signs would be really helpful. I mean just knowing, I'll tell you, as a dermatologist I'm unique in that if I find somebody who doesn't have a blood pressure and they're a young person I get their blood pressure because they don't have a primary care provider. Most of the people I see between late adolescence and the ... of life don't have primary care providers. So this notion that there's a Marcus Welby out there, who spends a whole hour every evening devoted to the care of one person, that ain't my world. So even being able to know that yes, indeed, the blood pressure was taken and I can easily get that. That might be even lower hanging fruit. So there are other domains where you should be able to share information.

Edmund Billings – Medsphere Systems Corporation – Chief Medical Officer
I think medications is where you should start. You've got the most infrastructure there already. You've got a Surescripts network. You've got lots of content. You've got lots of, if you look at it compared to other domains, they're not as mature or they don't have as much tools in place already and you could leverage that and say, "If we could just share current medications or medication history and we could use that that could be a great cornerstone.

Hans Buitendijk – Siemens Medical Solutions – Senior Product Manager, Healthcare IT Division
Whether it starts with medication problems, allergies, either of those topics for the community to decide which one has most value in the short-term and has the least amount of challenges on some of the policy procedure questions. From a technology perspective, I would first challenge the question of the assumption that you're making that it has to be in a new format. So as part of that, the question is what are we really trying to achieve? Are there opportunities to expand on what we currently have and where that breaks, start to figure out what kind of ... needs to be in place? I'm not sure whether we have to make an assumption up front that it has to be a new format. One of our responses included utilize the format that it's currently in. The SNI framework is fine to be explored. I think that the Direct Project was a very good example of that where certain assumptions were at the start of the project and the participation and the exploration of the issues at hand, trying to solve them, came up with solutions that, in part, used existing capabilities for certain aspects. So I would not want to predispose what the answer is going to be. I'd rather build on that and determine what kind of metadata is really needed. Could I expand the documents or not? Why not? So I would start a little bit more on a blank page in that regard than making the assumption that it has to be a new format.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
That's a fair statement. I was trying to get to the possibility of it as most ... Mike?

Michael Stearns – e-MDs – President & CEO
Yes. I would agree. I think what we need to do is set it up so we use existing profiles wherever people can agree upon and then use them in a word, to extract the data and then present that to the clinicians in a safe environment, but also give them access to the document. Just do a comparison and see what comes across, what their interpretation is of the parts data versus the original document that contains more context. Do you have an idea of how safe it is? Then learn from that.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay. I'd particularly like to comment about the blood pressure, because Stan Huff's favorite example of molecular data would then be enshrined in our work.

John Halamka – Harvard Medical School – Chief Information Officer
Do you have any follow-up questions ...?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
That's okay. I'll pass.

John Halamka – Harvard Medical School – Chief Information Officer
Okay. Well, we have 7 cards, 30 minutes. I know Judy Faulkner has put up her card about seven times and so it's your chance. Go, please.

Judy Faulkner – Epic Systems – Founder
Okay. A few things here: The report has been called visionary many times. I haven't heard the word execution be used. I keep thinking of the Gartner magic quadrant and the vision and execution portion of that quadrant and then the vision side of the quadrant. What we're talking about a lot here is how do we move it into execution from vision. Just a little comment. As a technologist, I think on the medical side sometimes I hear folks say it should be easy. We trust you technology folks to just be able to do it and so I would like to give my little list of ending diabetes, curing cancer, fixing spinal injuries—

M
We'll get right on that.

W
You can do it, Judy.

Judy Faulkner – Epic Systems – Founder
So, my question to the technology folks is a base question I think of what's been going around here, which is is it worth it. What we always have to do, I think, is prioritize, not just look at something independently and say, "Can we do it? Should we do it?" But is it worth it? There is a price. What is the cost? Do you have to buy middleware? Do you use what you have? What's the cost of the middleware? What's the cost of putting it in, supporting it? What about all of the interfaces that have to be written? A big interface job, dealing with the privacy issues; dealing with the patient identification issues; dealing with the universal exchange language. My question is if you want to improve healthcare with the technology you are currently working on, suppose this report hadn't come out. Do you think this transcends and supersedes the directions you were going or do you think the directions you were going will bring more value in the foreseeable future than doing this?

John Melski – Marshfield Clinic – Medical Director, Clinical Informatics
Good question. A difficult one to answer. I was recently just reading an article about how long it took when the Wright brothers took off until the time that people started to realize that the usability of the controls in the flight were terrible. It was about 1945 or something like that. So it took like 70 years from the time the Wright brothers first flew before you had really planes that were safe and the instruments, the human engineering had been resolved and all of those types of things. So was it worth it in 1920? Was it worth it in 1930? Clearly, it's worth it. The question is at what cost and at what time. So it's really a good, fast, cheap triangle. That's why I think limiting the scope to something that's doable because I'm afraid that if you reach way, way beyond your grasp you'll have the paradoxal effect of setting everything back. This is history through my lens and it may be inaccurate, but stories are good even if they're wrong.

... tried to put in electronic medical records and the culture wasn't quite ready and pushed it and actually set his effort back because there was so much hostility towards the concept. So that's what I'm concerned about is that if you make these promises and you don't deliver you discredit all of the good stuff that can be done and so there's a huge risk here as well as a huge opportunity for benefits.

Paul Egerman – Software Entrepreneur

... I didn't take this out of the context of the roadmap that we're already on with meaningful use and driving adoption. If we don't assume that you need health IT to improve quality and control costs then you need to put this vision in that context. To the point is that stage one had share or CCD or share or CCR, well that needs to have not just the data in it. It has to have semantics in it if you're going to use it on the other end. If you put the right incentives on both ends of that, which there should be, sharing information controls costs and supports the continuum and it's valuable. If you incentivize that value the solutions will get worked out. If you create a big vision that's a rip and replace I don't think that's where we are. I mean we're not talking rip and replace here. This will evolve just like everything else over the last decade, but I think putting those pieces in place I didn't see it being written by a different group. I mean it was their members on both sides of this saying very much coherent with what we talk about when we talk about interoperability within meaningful use; that it needs to have the core value in the data, in the transport and not just the data not be readable or analyzable on either end of it.

John Halamka – Harvard Medical School – Chief Information Officer

Paul, thank you very much. Charles Kennedy?

Charles Kennedy – WellPoint – VP for Health IT

This is really a follow-up onto the question Judy asked because, Hans, when I read your written testimony I actually found it very compelling. What I saw was you said, "We believe the tag data elements in XML alone are not magic bullets," that XML has been around and it hasn't substantially reduced the challenges involved in determining the right structure for particular communications. But then you went on to say, "Tagged data and XML are not the issue," and you talked about semantic interoperability, context specificity, etc. Those are all things I largely agree with, but I think the thing that surprised me was then when we got to the executive summary and you made your recommendations three of the seven involve data tagging and validating PCAST concepts. So I guess what I'm trying to get clarity around is is testing the PCAST concepts a step forward to a better flight control system or is it a dead end in and of itself. I don't think I've got clarity on that yet.

Hans Buitendijk – Siemens Medical Solutions – Senior Product Manager, Healthcare IT Division

Let me see where we can clarify, because I can understand the way that you presented that that you might read that into that. I don't believe that the type of communication that is being proposed within PCAST in itself is a dead end. It is an unnecessary type of communication. ... report depending on how it's being read one might have interpreted it and we certainly were among those that felt that it was proposed as a replacement of and that may not have been the intent. As long as it's not the intent it's very much a complementary way of communicating that if you build up from where we have been in the past, where we tried to connect providers within one organization and tried to figure out how to resolve some of the vocabulary, the transactions, the formats, etc. We're now just effectively progressing that from the provider internally to the provider externally from a directed push model, where we know who we are, who we're communicating with, to one where we believe there is opportunity and we would agree with that. There is opportunity to get more value out of data that's out there, to explore that ... the variable. Lots of challenges to be addressed, as discussed today.

But as we go through that, as you're trying to then figure out at what level and how am I going to now put that data together so it's consumable I need to address questions like tagging. Tagging is not in itself the issue, but what the tag is. What's the level of granularity? What's the structure? At what level of decomposition are we going to sit? Back in the '90s we started with a definition of pharmacy prescription that very explicitly had one transaction of an unstructured prescription. That was intended there because the initial entry of that information was typically unstructured, free text so that the pharmacist could encode it. We have seen over the last number of years, 10, 15, 20 years, that the place where the structure is starting to be put in has moved from the pharmacist much closer, if not in a lot more cases, by the clinician. In the process the transactions didn't change really. It's where you put the data that changed. Therefore, having agreement on what is that level of granularity, where are we going to put the data and, therefore, in this construct of having tags available that I can query, what that tag means and

having definition around it is important. But the act of just defining the tag or allocating the tag, that's easy once I've figured out the discussion in front of it. It's that discussion that's the challenge.

John Halamka – Harvard Medical School – Chief Information Officer
...

William Stead – Vanderbilt – Chief Strategy and Information Officer
I'm going to divorce the subject of a DS from the subject of a UEL, a universal exchange language, and really focus on the latter concept. We've heard a lot about document structured information versus molecular, atomic structure. I'd like to approach it from a slightly different perspective and look at a set of four use cases. Use case number one is interpretation of a discharge summary or consult note as a document. I think we've all discussed and agreed that it's important to know the context, the narrative text, as well as the clinically structured text in order to interpret that document.

Problem number two is getting to an up-to-date med list, an up-to-date problem list, an up-to-date set of recent labs for the patient. We could go on and on. The notion that in a clinical care setting where patients receive care in multiple locations that pieces of that are going to be scattered around the care environment, so there's a need to aggregate for a clinician's purpose or a patient's purpose a single, up-to-date list.

Problem number three is with respect to a population of patients within a particular domain for quality improvement. Problem number four is with respect to taking summary level data across a variety of settings of care to provide either public health or research analytics. Where I think the PCAST was tasked was really on problem four. The question that I'm asking, a long-winded intro, is do you believe that there is a ready to use, tractable, universal exchange language that can express all four or can be used for all four use cases?

John Melski – Marshfield Clinic – Medical Director, Clinical Informatics
I think, Bill, it's a question of this issue of the universal language, as I understood it in the PCAST Report, there is no intrinsic problem with that. That's a very good vehicle to go forward. It's a problem, exactly as we heard, it's exactly how do you use that language so that you can reconstruct meaning when you get the information on the other end. So again, problem lists are one of these things that in the common sort of understanding this problem has been solved. Let's move on.

Well, hello. It's not been solved. Who adds to the problems? Who takes it away? You heard about the emergency room visit where the drug-drug interaction is not the issue. How does that get updated? Do they do a complete drug inventory in the emergency room? So it's extraordinarily complicated.

I think that the language, to my understanding of the technology, is not the issue. It's exactly what gets marked up and at what level of detail and for what purposes and how do you use that data that's collected for one purpose and reuse it for purposes that it was never intended. That's very, very tricky. I mean the hallmark of science is systematic observations. We have lots of observations in medicine, but to describe them as systematic is wishful thinking. They're haphazard. It depends on whether you get paid. It depends upon whether you're willing to come in. It depends on whether you're willing to come back. If the 20% who don't fill their prescriptions, and that's a conservative estimate. What we do is anything but systematic and so there are all of these other issues that surround what exactly you're marking up. What exactly does it mean in the context of being able to understand what exactly is going on?

Hans Buitendijk – Siemens Medical Solutions – Senior Product Manager, Healthcare IT Division
... a comment and a question, kind of an exasperation maybe a little bit; why is there not one single model that everybody adheres to across all of the different systems? Similarly, I think with these four examples we can add on a lot more. It's that there is not a single agreed to language or model on these and there are different perspectives. As we have grown out of different histories of solving individual problems and technology being only able to be applied in one particularly area, not applied across the board and we

have started to grow together is that we finally find ourselves saying, "You are doing it that way. I'm doing it this way. It's different." We have to bridge that. We have seen it within providers. We have seen that between lab systems, pharmacy systems, radiology systems, etc. with the EHR. We now have to synchronize that. Now we're seeing it across providers where some of these challenges are compounded, so can we say that there is one single language? Some might say I believe my language is the one that could do it. We certainly don't have a single or agreed to language so that we can consistently communicate whether something is part of a discharge summary, whether it's part of data that goes to public health or of a secondary use that the data that I'm sharing is consistently expressed the same way so I know what it means.

M
If I can repeat back what I think I'm hearing and tell me if I've got this wrong: What you're saying, I think both of you are saying, concentrate on the semantics first; that the exchange language in some sense is notation and that our problem is actually a semantic problem first and foremost.

John Melski – Marshfield Clinic – Medical Director, Clinical Informatics
Yes. I would say yes, but—the low hanging fruit does require concentration on the semantics. But there are other things that I don't think in my lifetime I'm going to see the semantics solved. So we have to have the ability to deal with both types of data.

So, for example, I think that it's within grasp to have adverse reactions to drugs, sort of somewhat standardized and that's why I chose it as an example. On the other hand, how about all of the other allergies that are important, like you're allergic to the tape and you're going into the hospital and you should get that tape. It turns out that, well, what do you mean by tape? Is that Micropore tape? Is that plastic tape? Is that paper tape? Is that adhesive tape? Are we going to wait until we standardize on how you do tape allergies? How about the patient who comes in and says I'm allergic to the following 20 things and some of them you've never heard of and they're not in your vocabulary. Are you going to disregard that? That's not very patient-centric. You're going to have to accommodate that.

Now, something near and dear to me is I do a lot of contact allergy testing. There's no standard way to represent a lot of the chemicals that I test to, and so these are arbitrary. So the thing that attracts me to the PCAST thing is that it doesn't say that you have to use a structured vocabulary or agreeing on a vocabulary is unimportant, but it would be terrible to throw the baby out with the bath water, because in some domains, like non-drug allergies, where it might be useful just to capture something. That's important and needs to be transmitted and may not be a standard vocabulary and may never be a standard vocabulary because it's open to so much imagination and interpretation.

On the other hand, the drug allergies are a much more defined universe. So, you want to capitalize on lexicons that are ready and ripe to have the magic happen, but you also need to accommodate those vocabularies that are not yet there and, unfortunately, there's a lot that's in the latter category. So, you need both. It's not an either or thing.

John Halamka – Harvard Medical School – Chief Information Officer
Well, I know we want to get to the committee members, so Tim and then Dixie.

Tim Elwell – Misys Open Source Solutions – Vice President
I read it the same you did when I first went through the report. It looked to me that the recommendation was throw it all out and start over again. My esteemed committee members here have convinced me otherwise, that it's more of an incremental type of approach. But what I am hearing is that there is consistency and concern about the time frame. There is also agreement, however, that there are some

visionary opportunities here and that we can take some of these things and add to what's already going on.

We also had talked about the concept of pilots and I think Edmund brought up the concept of a prototype, all I think very good. In fact, in light of what's going on with Connect:Direct and with merth and other types of programs in open source as examples, and how collaboration can work, all those things I think are consistent with the incrementalist type of innovative road to future success.

I guess where I'm going with this is how will that help us now? What would be your recommendation? How would you structure that type of strategic innovation in light of the good recommendations that have been made, some of which will fall along the wayside and others will be improved upon and some will be extended, etc.? How do we do that? Is, for example, the open source model a good example of one way of doing it? Furthermore, when you threw up your numbers here, Edmund, and in light of the economic impact associated with what potentially could be, we're talking about billions and billions of dollars additionally to be able to make this particular strategic plan come to life. Is there something that we can borrow from this collaborative type of mechanism for us to be able to drive down some of the costs?

You had a very different model here that you threw up, right? I mean, if I went over to Siemens, would that be something that could be adopted in a corporation, such as yours to be able to dramatically reduce the costs associated with, for instance, interfaces, which is a huge impediment when we're talking about rolling out community solutions? Any suggestions there, is there something that you could recommend to the panel that we should consider in our recommendations?

Edmund Billings – Medsphere Systems Corporation – Chief Medical Officer
Well, I think it's just, to go a little bit further on my comments is that the lack of interoperability or the challenge is it's a business opportunity for many companies and it's a barrier to adoption for many organizations. So, what we don't want to do with PCAST is create another layer of challenge and the open source model has a way of commoditizing things that need to be commoditized for the greater good and the cost and complexity gets commoditized and that's not true, necessarily in other models. So, if we're going to create something of value here and do it fast and do it affordably, the current HL-7 is not affordable by the market I'm serving, unless you do it the way we're doing it. So, that's the current, not the future, and that's probably a version ago, so we need to get real here if we want to have this thing roll out.

I say you go back to the meaningful use information sharing criteria and you push PCAST into that model and you say how can we make semantics flow and how can we achieve some of this vision within the first instances of sharing and then you put open source projects around it. That's how you accelerate this into 2013. You have to put dollars; you have to put a business model around it.

John Halamka – Harvard Medical School – Chief Information Officer
Well, thank you. Dixie.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
The comments that Dr. Mattison said in the last panel really got me thinking, particularly about the fact that genomic signatures are making their ways into EHRs. I know he's right about that and I also know he's right that as the genomic information becomes more available through EHRs that the clinical decision support will become more and more dependent upon it and there will be liability issues associated with it. I think that this is like to happen much sooner than we think and that we would like to think it's going to happen and it, obviously, has privacy implications. So, I have two questions. The first is, what is an atom within a genomic signature? Is it a gene sequence or is it the whole signature?

Number two, is your EHR, all of you that designed EHRs, how does your EHR accommodate genomic information?

John Melski – Marshfield Clinic – Medical Director, Clinical Informatics
This is, obviously, a work in progress and I would not say that we are necessarily leaders here, but genomic information in small pieces is already there. There are certain laboratory tests that detect enzyme deficiencies, bioperine methyltransferase and HLA types and blood types and there's a long series of laboratory tests, which have a fingerprint kind of quality to them in terms of identification. So, in a sense it's interesting that this problem should be raised as a new problem because in a sense, with the right resources, it's an old problem with the laboratory testing that we already have, that already contains some things that are uniquely specific to individuals.

Edmund Billings – Medsphere Systems Corporation – Chief Medical Officer
I think I would answer that in my institution it's at the biomarker level rather than the ATGC level.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
So, that's an atom?

Edmund Billings – Medsphere Systems Corporation – Chief Medical Officer
Right. So, it's just exactly as you said. It's the actionable information as opposed to the data.

John Halamka – Harvard Medical School – Chief Information Officer
…. So, I know David McCallie has been waiting very patiently and I see we have about five minutes left, so please go ahead.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
The PCAST Report, before it came out if you had asked a group of informaticists or this group of panelists what the universal exchange language was for health care, after you got some quizzical looks, I suspect most of them would have come out and said it's CDA, Clinical Document Architecture with v3, HL-7 v3 as the mark-up language. In terms of general purpose toolkits, that's probably the closest that we have. The PCAST Report itself kind of damned by faint praise the CDA, it basically suggested that maybe it was a starting point, but not adequate. In your submitted reports, I believe all of you endorsed sort of sticking with the current approach and suggested possibly enhancing it.

So, I just want to drill in on that with respect to the CDA and, in particular, well, let's just say CDA broadly, not CCD as in C83 specific for summary data, but CDA as a representative approach to marking up clinical documents with structured data. Is that an adequate approach or do we need something that is just an improvement of that or do we need to start over in that space? I know it's a tough question, but I'm just curious to know, whoever wants to take it.

Hans Buitendijk – Siemens Medical Solutions – Senior Product Manager, Healthcare IT Division
That's interesting question and it is raised a number of times in various different contexts. Start with the notion that a document is a reasonable representation of something that we need to communicate that has come about beyond the traditional messaging that we have been doing for quite a while. From that perspective there is a very good use case and very good need to be able to exchange a document.

So, starting with that part of CDA I don't think we're looking at a challenging task. So, the question is that is the particular way that in which it's being stressed, is that a good way, a bad way, could it be better? I'm sure there could always be things that could be better in that, but given the progression that we're on right now, I'm not convinced, based on the arguments that are being made, that rather than progression with where we are with CDA with the family of documents that are included in that. The interchange of sections and components across those different document types where essentially a great level of consistency can already be attained across different types of documents that we also would like to see, that it should be reasonable to progress that and understand better what some of the challenges are moving forward, by it's not based on the use cases that are presented.

One could say that there's a large investment, but okay, so be it. But there is from the community to come to an agreement on what level of structure is needed to put proper content in a document. There's been a tremendous amount of investment in that to go through. You effectively are going to start the discussion again if you're going to go to another format, another structure because we still have to agree on the same topic; what level of structure, what content, what vocabulary, how are we going to put it in there, what level of granularity? So, we are effectively going to start on the side with something new. Are there opportunities to enhance? Surely, over time and as the experience gets out there I'm sure that it will morph. Exactly how? Don't know. We'll find out.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
So, I think I got lost in your first answer. You think that CDA is enhanceable or you question the assumption that it's enhanceable. I lost.

Hans Buitendijk – Siemens Medical Solutions – Senior Product Manager, Healthcare IT Division
No, I question the assumption that it's not efficient for it to get started and I believe that as it has progressed to date that there are opportunities to enhance from there, not necessarily throw it out. It doesn't mean that there's still lots of things to be learned on that.

David McCallie – Cerner Corporation – Vice President of Medical Informatics
Anyone else care to comment on that, the CDA question.

Michael Stearns – e-MDs – President & CEO
Just one quick question; seems like there's a lot of commonality, but there are some differences, so it seems like the next step should be a sort of dialogue with the PCAST principles. If there is a PCAST oracle in the room, please speak up. We're trying to identify the intent here a lot and I think there needs to be open communication. If we disagree, then I think that's fine and then we move forward with some testing.

John Halamka – Harvard Medical School – Chief Information Officer
Great. Well, you actually have the co-chairs of the PCAST Report sitting next to you, so Oracle A and Oracle B. Well, we are at time and I know we are being slavish to the timekeeper here. Let me summarize some of the gold start thoughts. How do we maintain the context of the encounter and at the same time think of something more atomic than a document? That's a challenge.

How do we capture data structure and what granularity do we capture, what vocabulary do we use? How do we ensure meaning, especially as data outside the context of a document is exchanged for different purposes than originally intended and do we need a detailed clinical model if the receiver is going to be able to interpret the data that is sent in less than a document format?

Then we need to separate syntax and semantics, so the universal exchange language may be a container, but the semantics there may be multiple ontologies and vocabularies that are used within it. They're decoupled and we don't need to actually get every item in medicine and the knowledge base that we're trying to codify in a full semantically interoperable form to begin.

I think Judy highlighted the question we need to ask ourselves is what is the burden, what is the time frame, what is the priority, given everything else that is going on? And, of course, ideally if in the context of meaningful use Stage 1, 2 and 3, 5010, ICD-10 and everything else we're doing, if there were some low hanging fruit, like medications being transmitted from point a to point b for multiple use that we would have done anyway, then that would be ideal. But changing direction or adding significantly to what we're already doing will be challenging for the technologist to have to cure cancer and spinal injuries and a few other things along the way. So, very good.

Well, thanks so much, everybody and let me turn it back to Paul.

Paul Egerman – Software Entrepreneur

Thank you very much, Dr. Halamka. Terrific summary and great panel, so thank you very much to all the panelists. It is interesting, particularly to hear John Melski's comment about Octo Barnett. I was fortunate to have had a chance to work with Octo in the early 70s on some of those early medical record systems. It's very interesting some of the challenges we heard at that time were similar. People would say, well, if you turn this all into data on computers it loses a lot of the context of the paper record and so there were some similar comments.

Panel number six is, it's really not a panel so much as one of the previous speakers who was asking for, was commented a PCAST oracle, and I'm not sure oracle is the right word, but we have Craig Mundie here form Microsoft. But we have Craig Mundie and Christine Cassel, who are the co-chairs of the PCAST Workgroup and, as I said before, they're very gracious to spend the amount of time they spent and changed their whole schedules around to participate so we really appreciate that. And Carl Gunter is going to moderate this panel. These people do not get limited to five minutes. We should have a little bit more flexibility.

Carl Gunter – University of Illinois – Professor
I was pleased to be relieved of the need to cut you off in five minutes. So, introductions, it's Christine Cassel, President and CEO of the American Board of Internal Medicine and the ABIM Foundation and Craig Mundie, the Chief Research and Strategy Officer of Microsoft.

Christine Cassel – ABIM and ABIM Foundation – President & CEO
Okay.

Craig Mundie – Microsoft – Chief Research and Strategy Officer
They're starting the five minute clock.

Christine Cassel – ABIM and ABIM Foundation – President & CEO
They're starting the five minute clock. I'm going to ignore it. Okay, we'll just start there. I just want to respond to your nice statement about our making an effort to be here. I think we really appreciate your inviting us and we really appreciate the depth and extent that ONC and the various policy groups have gone to to try to understand our report and try to think it through. We worked very hard on this for more than a year and I think what you've heard during the day today is that we all share this same goal of getting to a better place in improving both the quality and the affordability of healthcare and that's really our goal here.

So, let me start. We do have some slides here and we're not going to go through all of them in all of the points, but just as we put together this presentation we realized that we actually I think responded to some of the questions that came up over the course of this discussion today. So I'm hoping that we can do that and then leave ample time for your other questions. So, the main thing on this slide—and I apologize to the panel at the front there; oh, you can see the screens, great—that there are two little icons there. One which is the front page of the PCAST Report and that in the comments that I'm going to go through and that Craig is going to go through, that denotes something that actually comes from the Report. Then the little professorial person there is kind of our own opinions and additional information that we wanted to put on that Report. That icon was initiated by William Press, one of the co-chairs of PCAST computer science professor at the University of Texas at Austin, also a member of PCAST who was also instrumental in the work of this working group and in the report.

I want to say a couple of things about the report just so you understand its providence—we've been talking a lot about that word today—this report was built out of a working group. Many of you came to talk to the working group during the course of our work and many people outside of PCAST had input into it. Then, ultimately, the report was written by PCAST and endorsed and approved by a consensus process of all 20 scientists who are members of PCAST and Craig and I are two of those. So, it isn't really our Report, it's PCAST's Report. There was a lot of vetting and a lot of discussion that actually I think we've made it a much better report.

The second thing I wanted to say is that when the president asked us to do this report, and it came from him, not from us, he had already made this major statement of this investment in ARA and in HITECH. This in no way was meant in any way to under-value or undermine that investment or all the work that it has generated and all the progress it has generated among the entire healthcare world and certainly in the administration. He's been the greatest advocate for this. What he asked us is—you know, that old question, look where the puck is going. We've made this huge investment. Tell us what's beyond that. What should we be looking at to make this really work for improving quality of care and reducing cost of care, which is right now is just really the hugest issue in front of the nation. So, that was really our assignment was to say take where we are and look where we're going. So, I think those of you who are arguing about does the report say rip and replace or does it say build on what we have? I think we very much are not saying rip and replace. That wasn't our assignment and that wasn't our recommendation.

So, let me just make a couple of points here. First, a disclaimer; I'm not a computer scientist. I'm a physician, an internist and geriatrician. I lead an organization that's responsible for physician standards for board certification in 20 different subspecialties of internal medicine for 200,000 physicians in the United States and part of the community of sort of independent, private sector, quasi-regulatory standard setters, who use a lot of quality data who are asking physicians, like many other players in the healthcare world, to report data to us about quality of care.

So we're very conscious of the burden of those demands on practicing physicians. But the first thing I want to say is the focus of this report was not primarily about providers. It was primarily really about patients and about what works for patients and looking more broadly at the patient perspective. Not just a PHR being something the patient might import from the doctor's office, but really getting patients engaged in using and even creating some of their own data and, as was mentioned earlier, identifying more actionable ways that they can both increase their privacy, but also get more involved with their own care.

But also, very importantly for providers, I think that the issue you heard earlier today about workflow and costs for physicians in their offices. As wonderful as Kaiser and VA are, it's still a minority of physicians in the United States, 50% of our diplomates are in practices of less than five people, 20% are in solo practice and those are the people who are having the greatest struggles with the current adoption. They want to do meaningful use, they want to report measures, but they have to stay two hours in the office after work in order to re-engineer the reporting of these measures. There is nothing that occurs in the process of patient care with the current models of most of these electronic systems.

So what we were looking at was a way of accelerating that change to make decision support more available, more flexible and to really make the measures that come out more flexible. That's something, only once or twice today have we heard the term CMS mentioned, but there is a very important partner on the other side of this equation in terms of all the federal reporting and that's CMS. As you know, CMS, too, is taking a deep look at its information systems and all of the constraints of what kind of measures can actually be used in these reporting mechanisms and as a physician, I have to ask that question. How meaningful actually are these measures given the limits of the numerator, denominator arrangements that are currently possible, so greater flexibility, greater data liquidity is really what we're looking for that happens in the course of patient care, not as extra work or not as an additional staff person in your office.

Then, finally, the public benefit here. The president was very interested in that because of being very interested in tracking epidemics. When we started this work, it was in the middle of H1N1 and the concern about that, so it isn't that the PCAST Report puts the public health above the patient care goal, but realizes that there ought to be a way to achieve both, once we get into an age of electronic information. So, that was the component there and in terms of the research chapter, we are very aware that that was very limited and that we didn't answer all the methodology questions that the researchers have answered, but we said there ought to be a data stream that would allow a lot more efficient use of this data for research purposes.

Then in terms of innovation, again, we weren't thinking mostly about commercial uses or monetizing the data in that sense; we were thinking about innovation for the apps, you know, for the kinds of things that the patients and the doctors could use that would be more creative and that certainly would begin to

emerge. You can call it middleware if you want, but we probably can't even imagine some of the ways in which medical care could get better if we had more flexible uses of the data.

So, are there barriers to these good things happening, particularly in the current environment? Well, PCAST believes yes, but clearly all of you do, too. We heard that today. The first one I just want to acknowledge, my compatriots, the other physicians who spoke to you today, we are aware that the perverse incentive structure environment that we're in really is a major problem and we are very aware that this group isn't set up to solve that. Meaningful use can help a little bit as a way of getting in the game, but unless there are changes in how we pay for healthcare it isn't going to be sustainable and you heard other people this morning measure that. We do have a chapter on that in our report, so we very much are supporting a very aggressive movement to ways of compensating healthcare providers, doctors and hospitals, that really provide a better incentive for value rather than volume.

We also think that the base of legacy systems that are now in place not surprisingly are working within that system. So it mirrors in some ways that incentive structure, that sort of vertically integrated system where you really need to make these bilateral arrangements with a lot of lawyers involved if you're going to share data with any other entity rather than making data sharing more generally available. Making the expectation that if you're a doctor, you ought to have all the relevant information about that data and that you should be held accountable for that. That's I think what is meant by an accountable care organization, but, of course, like me you're waiting, too, to find out what we really mean by that. I think conceptually that is the idea behind it and we're very supportive of that, but our current information technology environment really doesn't allow us to do that.

Carl Gunter – University of Illinois – Professor
I don't mean to interrupt you, I just want to tell you I believe this presentation is a presentation Bill Press already did to the workgroup. So I just want to make sure what we're most interested in hearing is understanding the implications of your recommendations to ONC's work as opposed to discussing the benefits because we really think there's a lot of challenges there.

Christine Cassel – ABIM and ABIM Foundation – President & CEO
Okay, so the last thing, I'm just going to hand this over to Craig, and I think what we want to do is really use this is why I was sort of trying to highlight the points that were brought up during the course of part of the meeting that I've been able to attend. So, really what we're looking for, and this is the technical list of issues, is a way to move forward without requiring wholesale replacement of existing systems, without requiring a central data repository and to be able to really build in those data protections for privacy and security for patients.

So, I'm going to turn this over then, Craig, to you.

Craig Mundie – Microsoft – Chief Research and Strategy Officer
Okay, thanks, Chris. So, just to finish a few of these key thoughts and then talk technically about some of the discussions today and how I think we think about them. As Chris said, I just want to reinforce that we started with the presumption that you really couldn't disrupt the existing systems, that the idea that you could discard them and start over again was just completely impractical. So, we were much more focused on is there a way to think about how to take, over time, all the data that exists in the existing systems and put it in a structure that would allow it to become, over time, gradually more exposed to these new types of applications. We felt that if that could happen we would ultimately be in a better position, that more people would be able to develop software, whether that was through the open source mechanism or commercial mechanisms, that PCAST Report is neutral as to how those things might evolve.

Our view was that there was a set of things that we had to stitch together and I'll comment on these mostly in the form of trying to answer the questions that were raised today. First, we wanted a way to describe the existing data and clearly there's been a huge amount of work that's been done on standardization on certain record formats. But our view was that that would never be able to catch up with the rate of change and that we therefore wanted a system that would allow the immediate

incorporation of evolving sources of data and that they could ultimately be codified over time. So the idea of the universal exchange language or the metadata description was to create a way where people could introduce, in a sense, their own concepts or descriptions of the data as they introduced it where it wasn't yet standardized or codified in some way. Then over time, the actions of standard bodies or the actual use would lead to more codification.

So we were looking for a balance between not only the structured and unstructured, but that which was new versus that which was more fully evolved. Due to the political issues primarily, but also some of the comments that were made earlier, our feeling was that we should use a way of identifying people without trying to have a globally unique identifier and by that we really were talking specifically about the idea that there would be a centrally issued, per citizen identifier.

That said, we were quite interested in the course of our discussions to think about as the patients themselves became more involved with their own healthcare and, in particular, when many of them would elect some form of personal health record. Now, to do that they would be generating themselves a unique identifier that could be pseudo anonymous, but it turns out if they chose to use that as part of what they allowed their provider to use to identify their records, you'd have a global unique ID, but it wouldn't be one that was issued by the government. It would be one that was, in each case, selected by a person and some other mechanism would attest to its uniqueness. So that, coupled with the kind of things that I think John Halamka mentioned earlier, the Jeff Jonas type work, you know all of those things led us to believe that we would see a capability to provide appropriate uniqueness and identification and I'll talk a little bit more about that.

Another thing that we were very strong on and I think some of the questions that people asked related to, for example, the lessons from DRM, I think which Carol mentioned this morning. There are a lot of differences between the experiences there and I'll come and talk about them more in a minute, but one of the most profound is that this is a system that in our envisioning is, if you will, a closed system. The people who participate, except for the patients themselves, all have identifiers, all have robust identities for not only them as individuals, but the systems they use and even the roles that they perform and so the report talks broadly about the need for those robust identity mechanisms. That turns out to be a key component of why we think some of the things we think were largely difficult to achieve in the DRM environment for music, for example, may not hold in exactly the same way.

We also felt, and I think a lot of the discussion today talked at length about most of the model today is about push, whether it's a document or anything else, there are more or less ad hoc exchanges or things that have to have bilateral approval. We felt that that wasn't scalable and so the idea of creating an access model, which the report calls the DEAS systems, was the idea essentially building on what we've observed, for example, in the Internet at large that we now have, without question. The ability to index this data at any level of granularity we want, at any scale that would be required certainly for the entire healthcare environment and that that would provide an alternative access model for the data no matter how it might be described. Then we wanted a protocol to exchange this stuff in a highly liquid environment. So, why do we think that this was technically achievable now? In a sense, the broad Internet evolution and the technologies that have emerged from it have been used in other sectors and I think our view was that many of them could now be applied more directly in this area.

The first line of the things I note here I think is a particularly interesting one. I mean Web pages were described with html and transported over http. That led to a huge diversity over a fairly small number, evolution of the html language to describe these arbitrary Web pages. But that taught people that they really didn't want to just describe Web pages and so xml was created so that people could, in essence, make their own derivative languages and that's been well referenced in the discussions today. I think other things that weren't referenced, but I think are interesting to look at, the people who pursued the work in, for example, the semantic Web, have created RDS and things like OWL as additional mechanisms for formally describing ontologies and taxonomies. Much of the discussion here today was really about how do you maintain or describe the semantics?

I think that there are evolving more and more well accepted ways of doing that. One of the things that I've been asked a number of times since the Report was issues was can you give us some examples of other places where this kind of thing has been done at some significant scale. After thinking about it a bit, one of the things that came up more recently was how businesses have evolved in terms of financial reporting.

I'm not sure if you're all familiar with it, but there's a thing called XBRL, which is essentially the business reporting language. It's evolved, you could say from its very beginnings, its origins were at NASDAQ about a decade ago, but four years ago the Securities and Exchange Commission decided to adopt this and to formalize it. To some extent, in a model I'll say that isn't that divorced from what PCAST implied in its recommendation in terms of the role that ONC might play, the Securities and Exchange Commission actually funded the development of XBRL, if you will, as a universal exchange language for all of the financial reporting.

If you haven't looked at it, I'd encourage you to go that XBRL.org Web site and look at how this thing has evolved in four years. Interestingly, and I'll say more in the model that we envisioned in the PCAST work, they started and gave about 18 months to the Fortune 500 companies reporting using this thing and that happened two years ago and by this summer every public company in the United States has to provide all financial reporting data using this language.

In that same period of time, and I forget the count now, but dozens of countries have now basically with their own reporting standards all built their own taxonomies and they have a complete way that they govern the evolution of this stuff. I think it's interesting to look at that as a history and as an example; it also tends, if you go look at the—and the SEC is certainly willing to make their history and expenditures known, but the rough numbers that the PCAST Report talked about for what it might cost the government to sponsor the development or formalization of this initial basic universal exchange language comports reasonably well with what the SEC spent to get this XBRL thing going. Clearly, Internet targeted advertising has shown that the ability to triangulate on people is really quite high. That's created privacy concerns and yet on one hand it also makes it clear that identifying individuals given a reasonable amount of information in a progressive refinement strategy we also believed was quite practical.

I commented earlier about the DRM and what I think is the difference between this environment. If you think of the examples that were questioned this morning about music, for example; in that environment we didn't have a way of really knowing what the devices were that you wanted to put it on, we didn't really have a good, reliable identity for you as the user to which rights were being conferred. We didn't have any real governance model with teeth in it from a regulatory or law enforcement point of view to govern this thing and all of those are contributing factors to how well or not well that one worked.

In the report, we talk about the important requirement not just to approach the privacy mechanism through the metadata tags as the be all and end all. But that that had to be wrapped into a privacy framework, much as I think was referred to in the early discussion this morning and that has to include appropriate regulatory governance and legal penalties associated with the authorized uses of this.

We see data warehouse, app stores, superscalar data mining and machine learning; you know, I was thinking about this session today and people questioning how well we can really teach these machines to understand some of these questions. I turned on the television last night and was watching the IBM Watson on *Jeopardy* and it basically did pretty well in the first round, we'll see how it does tonight. But our own experience, my own experience to do this machine learning is growing at a very, very incredible page and it's important as you make a decision about how far this can be extended here, you realize the rate at which this is evolving and how it might apply to these particular kinds of things.

Broadband connectivity is getting pretty good, despite some of the comments earlier today about low penetration. There's no real reason to believe, certainly with wireless broadband where all cell phones in the next few years will be smart enough to provide some type of access that we wouldn't be able to assume a lot of this will come into play. We saw two critical leverage points for the government and I want to talk about these not just from a technical point of view, but also why we thought the government

needed to intervene here. Somebody, I forget where in the morning conversation, mentioned the question of the Report said well, we should tax everybody to make this happen and I don't think the PCAST Report actually said that we thought everybody should be taxed to make this happen.

On the other hand, what we believed is that there should be a market failure relative to the creation of the data element access services, in particular. The reason was, as somebody also mentioned in the earlier comments, you don't want the entities that are creating this access system through which access is controlled to actually have any responsibility other than curation for the data. They should have no commercial interest and should derive no commercial benefit from the knowledge of the data that they administer in these indices. That's exactly the opposite of how the large search engines and other things that have evolved on the Internet, where it's the ability to have direct secondary uses that derive from maintaining the index that pays the bills. So, PCAST specifically said you don't want that kind of environment. Therefore there will be a market failure. It won't emerge in a natural sense and therefore it is a legitimate role for the government to cause that thing to come into being.

We said it could be done in a variety of ways, at a variety of granularities and we were neutral in the report as to how that should ultimately be chosen and I think that this committee should contemplate that. It was our view technically that there's no real scaling limit from a computation and storage point of view relative to the capacity of any single indexing system, so it really becomes a choice of policy and operational considerations, redundancy considerations that would ultimately guide the designers of this system, in our opinion.

I think that another thing that we believed strongly was that because this system is not like the Internet, it's not open to the public. But rather is essentially a closed system where all the people who participate have robust identities and the claims associated with those identities can be granted in a variety of ways, from things like the certifying or licensing agencies at the state level, to the major employees in the healthcare environment. Therefore you don't have to treat all people uniformly with respect to their privileges in accessing the information in these systems.

Now the same should apply for the software that's operating on their behalf. We also believe that the universal language itself in terms of a bootstrapping mechanism should be initially specified, but our view was that it really just was a container in which a lot of the existing standardization work should be put into a set of ontologies and frameworks that would allow this to proceed forward. So the two things are not really a rip and replace, but rather one becomes an extensible container for much of the existing work.

I think John Halamka summed this up at the end of the last session, but I'll just reinforce that we felt that it was important to separate syntax from semantics. That we wanted to be able to build on all the work that's been done there, but also recognize that in terms of the formal expression of semantics that even the work that has been done has not gotten very far. So this idea of the exchange language as a container in our view was a place where you could, if you will, put three levels of work. You could put the stuff that's already been done. You could put the future aspiration to have a more formally specified set of ontologies and semantics, that would then describe that and the ability to have a steady flow of as yet unstructured, uncodified data in there where people can describe it. So, if I want to go to my garage tomorrow and create a new gene sequencing system that no one ever thought of, I should be able to put it out there with its own metadata description and whoever takes it up and buys the first one could basically annotate data that way. They don't have to basically get everything annotated upfront in order to create value.

I think another thing related to this was this question of whether things should be normalized upfront or what I call late bounder, or normalized late. I think it's a continuum, frankly, and in our work we didn't in any way try to say that because you would have metadata attached at the most elemental level, that you necessarily would neuter the existence of the document architectures that currently exist. To the extent that a document exists, it obviously, contains elemental data. Today that elemental data is typically no annotated independently at the level that we advocate, but there is no reason to believe that the atomicity, to use John's question of earlier, has to be only at some single data element level.

The atom is something that I think could be at a variety of levels and should be considered that way. One way that I think about answering the earlier question about how small is small enough was to remember that part of the reason that the PCAST Report advocated for the basic annotation of providence and privacy constraints at the smallest possible level was, in fact, to facilitate exchange beyond the point of care.

So, the idea—and I don't know whether it was Bill Stead or somebody said earlier today, maybe it was Wes—this system does not contemplate the idea that let's just say Kaiser Permanente, they have their whole system, it's running there today; they don't have to do anything to that system. So, you have to insert the PCAST mechanism into the workflow process of how the system runs today. But the idea was that you would extract, over time, more and more of the data from those operational systems and put them into a structure that would then allow them to be exposed through this indexing environment.

The analogy in my mind, and this is very sweeping, that I always thought about was when the Internet came along and people came up with Web browsers, all the companies in the world didn't throw out how they ran their business inside, but many of them decided that they wanted to essentially have a Web presence. What that meant was they had to go take some data out of systems that were inside the company, figure out how they wanted to describe them and put them on a Web page and then allow that Web page to be indexed so that people could find them.

Before there were indices we used to push it around, you know, FTP or people would send e-mail links with things that were interesting and that, obviously, didn't scale. So, here I think that we're talking about something by analogy that's quite related to that that says you've got all of the, I'll call it, maybe it's a HIPAA enterprise, whatever you think the boundary of HIPAA is today, within there we have this free flow of information. We've got the systems, clinical and otherwise and there's no reason to think that that has to be disrupted.

On the other hand, if you say that some data that's in that environment should be essentially annotated and indexable so that it can be viewed or retrieved in any of a variety of ways from outside, then that essentially publication for indexing purposes is what was implied in the proposal for the DEAS. So that's why in this thing here we talk about existing vendors, if you will, should have the incentives to publish their internal semantics. What that means it just creates an environment, it becomes easier and easier for people to take this from the internal system to some external system that could then make it visible through this private Internet kind of context. The privacy metadata here was basically the idea is if we're going to attach metadata down at elemental level. Another way to think about how small is small enough is to think about where you would alter the privacy constraint relative to what you think the patient's expression of consent or some overriding policy that would live on top of that.

So, one of the things that doesn't exist today, at least as I understand it—and I'm an IT guy, not a doctor—but is that many of the documents are sort of an all or nothing exercise. You get the whole document or you don't get the document and the ability to segregate the thing in that transmission and to have any different constraints on secondary uses is not, as I understand it, codified in those things as they existed today. So, here the goal was, again, to say well, let's attach metadata that defines these privacy objectives and then allow it to change over time.

Let me just offer a personal thought about the questions that arose in this regard today—I think Dixie asked it and others—is this thing statically bound at the beginning or does it evolve over time? My view is that, again, these are all design choices that the people who want to build and operate this system have to make, but clearly, we believe that we should have an architecture that allowed the gradual evolution of the interpretation of these privacy preferences by people over their lifetime and as different situations would arise.

On the other hand, we're quite aware of some of the constraints. Many people mentioned about the need for responsiveness in the way that the systems operate and much of what we anticipated that, in fact, we wanted a near real-time way to produce an entire patient-centered view of all the data that would exist. So there is always a tension in designing any system between one that says just keep going back and

check everything and something that says I've been told what the permission are and I want them to persist for a period of time.

Again, I think there are some illustrative examples in some of the low-level engineering of the Internet. For example, the lifetimes on IP addresses that are issued by a server within an enterprise. By controlling lifetimes, you can essentially pick the points at which things can be repudiated and therefore forced to come back for a refresh. I think that mechanisms like that, there are other ways of doing it, but I think that those kinds of mechanisms should be thought of as a way to have your cake and eat it, too; have something that's largely scalable in terms of when the policy attaches to a particular piece of data.

Again, my view is if you think of a piece of information that's existing in a clinical system, in one operating environment today, it's when you extract that piece of information and decide to move it outside that boundary for a secondary use, that's the point where you attach the then extant policy that governs its use. So, essentially it was only moved at that time because you knew why it was going and if you attach some lifetime to that permission then once it gets there you can use it for a while and after that you'll have to come back and see whether the permission has actually changed.

So, those are some ideas about how you can deal with the fact that we have a difficult engineering challenge between efficiency and adaptability. Yes?

Carl Gunter – University of Illinois – Professor
It's about half the time up now, so maybe we should move to questions pretty soon.

Craig Mundie – Microsoft – Chief Research and Strategy Officer
Yeah, we will. I'm getting there pretty quick. I think we talked a bit about the patient identity and record location and why we think that the technology is evolving to allow that. One thing that is here is that our sense was that over time you may find a case where you don't think that you can disambiguate people and at that point today you put a human in the loop. There's no reason to believe, I guess, even as you would engineer these systems that you couldn't put a human in the loop again and so I don't think that there's a fundamental issue there.

Just a couple of comments about data security: We recommended that the data should be encrypted at rest and be encrypted in transit, which is implicit almost. That's, obviously, different than the way it exists today. Again, I think the thinking was is that when the data is extracted for the purposes of presentation outside your current firewall, if you will, that's the first place where you would essentially cause it to exist in an encrypted form. Some of the testimony commented that it was impossible to search things in the encrypted space, and I think that's true, but searching and indexing are two different beasts and I think our focus was on indexing and not sort of exhaustive search as a way of identifying things. I won't comment any more on that.

Carl Gunter – University of Illinois – Professor
Very good, thank you very much. So, I will make the attempt to do the 30,000 foot view of what we just heard very quickly so we can get to the questions to get to the details. So, we're looking for a spot in the future where the puck is going after the number of current initiatives have laid in and we're not looking to rip out and replace things. When we get to where the puck is going we want to provide something that is benefitting to a wide range of stakeholders, including patients, providers and the public. There are some barriers in the incentives and the install base, but meaningful use can help us address some of those incentive structures. The capability we're looking for is to be able to produce a global view of the patient in near real time, while respecting data sensitivity and privacy.

What we need in order to do that is a description technique for the existing data, an architecture based on granular controls and an access model, among other things. You gave a list of 12 technologies and there are probably others that weren't on the list that give us confidence that this, which isn't being done now can be done, that the technology doesn't prevent us from doing these things. The solution proposed is based on two new things; the universal exchange language, which is to be viewed as just a container and the data element access service, the DEAS, which is the search and access control capability for this.

There is a belief that the government needs to play a role in this happening; it's not just sufficient for there to be private efforts on this. That the DEAS and UEL will entail, if they're to be effective, some new ideas in privacy, security and other areas.

So, that's my 30,000 foot view for that. So, I wanted to kind of proceed to a couple of questions to get us warmed up. So, looking at the PCAST Report, I'm sure I'm like a lot of other people looking at it and thinking, hey, that's a really good idea and looking at other places and saying that's a really good idea, but I don't see how you would do that.

So, I'll ask you one question that was an example of the kind of conundrum that some people have encountered looking at the Report thinking, they're getting started here, but it's hard to see how you would actually do this. Example here is looking at the question of privacy and search the DEAS has to do a search and it does this on the metadata. The metadata is some sort of description of something that is held back from the search engine—correct me if I'm getting any of this wrong—but the metadata itself to be useful is likely to have a lot of privacy sensitive information. Even the mere fact that a particular institution has data could mean a lot. So there's a question of how do you deal with this chicken and egg problem of I need to be able to do a search, but if the search is to be of any value it has to have access to something meaningful and if it has something meaningful that it has access to then privacy will be affected by that.

Craig Mundie – Microsoft – Chief Research and Strategy Officer
I think part of the answer; there's two parts in my mind the way I think about this and Chris can add her own thoughts. The first is the people who have access to the search system are people who are authorized to be involved, so it's not like Google or Bing or Yahoo! or anything else or any random person walks up and says, oh, I think I want to search on healthcare. So, this is essentially a system that's there only for people who are authorized users and to some extent even what they can do in the search system, at least in the way we envisioned it, can be governed by essentially the claims that are associated with that individual or that piece of software as a proxy for an individual.

Our view was you can mediate a lot of the access, sort of as you walk up to the door of the search system and since in this case, people who are given the privilege of using this are people who are thought to be legitimate players within the healthcare arena, you have to start somewhere. This is also way I said so much of the privacy stuff requires, as somebody called it a trust framework and that is not just the mechanisms that govern the access, but essentially a set of, I'll say, rules and regulations with sufficient penalties associated with the violation of those.

Another part that I think was mentioned many times today was privacy concerns that were really based on security breaches or the actions of an insider threat, you know, a trusted party who violates these things. No technology will eliminate all those problems and so you can't expect perfection; you shouldn't even strive for it. But I think what's important is that the penalties associated with breaking the rules have to be very substantial, just as they are in the case of national security and other thing. I think getting those things in balance between regulation law enforcement penalties and then the technology to try to make it hard, the combinations required to give people comfort.

Christine Cassel – ABIM and ABIM Foundation – President & CEO
Yes, and I would just add that I think this issue of authorized users is a really important one. We don't have an experience with that kind of framework, but let's compare it to where we are now with what we use. This very clunky HIPAA system, which often has leaks, has huge leaks in it in terms of patient privacy and protection as well as getting in the way of quite legitimate uses in the emergency room level, etc. So, I think what we want is to make it better, but, as Craig said, it isn't that we think this is totally perfect.

Craig Mundie – Microsoft – Chief Research and Strategy Officer
One of the things that came up over and over again in our conversations around it was the situations, the break the glass situation. I think John may have raised it first. He said, look, people can say all they want about I don't want anybody to have my data, but when they get hit by the truck, when they're out of town

and they end up in somebody's emergency room, and then you ask them if you were awake would you want us to have the data? It seems invariably that people generally say yes.

The other one I want to highlight that came out in one of the working group sessions that I think was very profound, one of the systems that we worked with, and this was, Mr. Melski said about the safe harbor question, when the patient withholds their information, what should you do? We asked this question to try to get at the policy question of one of the really big, well integrated institutions and I said to them, if your patient comes to you and says that they refuse to allow the use of electronic records, what would you say to them?

They thought about it for quite a long time and they said we'd have to tell them we can't care for them. That's very different than many people's historical systems, well, I'll just impose the burden of saying well, you have to do me manually. These people were thoughtful enough to realize they have no manual way to treat them anymore and therefore the tradeoff now falls back to really be the patient's tradeoff; this institution requires the use of electronic things. I think Deborah earlier said, hey, you know, I need a computer to help me if you want me to care for you.

That will be increasingly true in the world that the PCAST envisions with the arrival of genomics and proteomics and other things for the scale and the data and the desire for personalization can't be done by a human alone. So the idea that the computer has to be a partner in this thing was sort of underlying a lot of our longer-term assumptions and that also then comes back to how you have to think about this tradeoff and the exposure of that tradeoff to the patients themselves.

Carl Gunter – University of Illinois – Professor

Okay, thank you. So the second question—I'll keep it quick—is this one concerns the space of what's new here and have we seen things like this before that we can use as risk mitigation so we know it will work here because it worked somewhere else? So, looking at this, I'm a computer scientist. When I looked at the system, I wasn't as much struck by the UEL, which has been discussed a lot here as how would you put all that information into the UEL, as I was for the DEAS. So I was curious what kind of ideas you have, and I know you're not binding these things, I'm just looking for speculation, on what kind of business and governance model are you imagining for the DEAS? So, for example, with the UEL, you mentioned XBRL from the NASDAQ as a model and people have speculated on various kinds of things the DES could be like, the credit bureaus, the NASDAQ, the Internet, other kinds of things; I wondered what your thoughts on those things were.

Craig Mundie – Microsoft – Chief Research and Strategy Officer

This is a personal view as opposed to a consensus because when I look at how these large scale search systems were being built, there were two of them I had personal familiarity with. One are the very large scale Internet search systems and how they're evolving and there the issue isn't whether you are confining access to information, the public ones, their goal is to find everything and make it available to people. Although, what's interesting about it and I kind of view it as the inverse of the problem here a little bit. Increasingly in the search systems what you're actually trying to divine is the intent of the user because with a trillion pages index just going and saying, well, I found everything that had anything related to it is just an overwhelming data glut.

So more and more you're trying to figure out what problem were they trying to solve and then just give them that. A big part of that is done by machine learning and in my own view, I think a large part of what I might envision about how these DAES's evolve over time, any one of them, is that you want to take the technology of search. This does not just apply to the scale of the Web publicly, but if you look at it now a great many companies are indexing everything that exists within their enterprise because they want the same facility to get at whatever is in the organization as the Internet implies they can get outside.

But inside they find that they do have constraints on who can see things, and so they start to basically attach some type of controls, whether they are access control lists or other things, or ultimately role-based permissions to say, you know, you can search, but only certain things will be returned. So I think if you look at what's happening in enterprise search where there are constraints on who can see everything,

you know, there are different levels of sensitivity, and you look at the machine learning models that are being applied to help what to return and in what context to return it. I think both of those might inform an architectural choice relative to the construction of the DEAS.

I guess the second part of your question was more a governance question.

Carl Gunter – University of Illinois – Professor
And business.

Craig Mundie – Microsoft – Chief Research and Strategy Officer
And business; one of the reasons in the Report we said that the government should essentially, if you will, cause these things to emerge was because we didn't really want there to be a business model specifically around the access system. We felt it was to play too essential a role and was, as you pointed out in your first question, a place where there was coincident too much information that you wanted anybody to have any interest in that other than curating that for the purposes of operating that. So you could say our report recommended that there be a market failure in that regard. I think one of the earlier panels said if they have any commercial interest in using this stuff, you don't want them.

Christine Cassel – ABIM and ABIM Foundation – President & CEO
And we agreed with that.

Craig Mundie – Microsoft – Chief Research and Strategy Officer
Yeah, we agreed with that. And so that was why we said the DEAS should have no business model. It's a public good and the government basically should figure out how it wants to bring into existence and to maintain it.

Carl Gunter – University of Illinois – Professor
Okay, thank you very much. So, I see we have a bristling of questions now coming up. I'll start with the committee, so Wes, would you like to start us off?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Sure. We've got six questions and 25 minutes, no less than that, right, 20 minutes. I'm going to ask a ridiculously techie question this time.

Craig Mundie – Microsoft – Chief Research and Strategy Officer
Chris will answer it.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay. Then I'll ask you a medical question. Throughout the history of exchanging data it's been the case that the semantics described the structure. That is, whatever our current understanding of the semantics are we grouped data together, this was the over group, this was the under group; maybe we described the date, a year with two digits or maybe we described it with four because the semantics, we weren't going to worry about the year 2000, I mean all these different things.

All of our semantic assumptions ended up embedded in the structure and we've done better over time at making that extensible, providing that you're extending the structure, but not really rethinking the semantics. So, XML, well we could discuss how extensible XML is, but XBRL would be an example where the semantics of what a financial report is described the structure, the XML schema defines the structure. You mentioned something today where that's not true; that is, that the data is described in a very simple structure and the semantics are described by external ontologies and I'm talking about RDSL. Is that specifically what you have in mind for the universal exchange language is a way that frees the data from being limited in how it can be interpreted or re-interpreted?

Craig Mundie – Microsoft – Chief Research and Strategy Officer
Yes, I don't know whether RDF is exactly it or something else, but as I said earlier we fancied the idea that there were different classes of data that would require different levels of structure in the description.

The higher order you got the more there was real codification of the semantics of that and at the weakest end you'd just say, here's some raw data. John put it up there last night and he thinks it's useful.

And partly the discussion about is everything pre-normalized or late bound, you need the contextual capability to document. I think all of these just show that there's a continuum. When you want to perform a task, you want to be given back the data, the right intersection between you have the right to see it and the level of sort of semantic richness that's required to solve your problem. That's why I called, in the report, what we called the exchange language, I called it a container because we really wanted it to be a thing that started out very simple and was really a place where you could house a lot of these different mechanisms.

And indeed, I do think that one of the things that's different between the example you gave like the year or the Y2K problem and I think it's one of the really profound things that's going on now by all the discussion about metadata and everybody today, by and large, saying, oh, that metadata is a good thing. You go back just ten years and most of the structure, most of the semantics were actually in the code, they weren't even in the data.

So I think what really happened and I'll say the Internet taught us a lot about this was to say you want to separate the protocol for exchange from the format of the record. You want to take the interpretation of the record and have metadata that describes what's in that thing and that those things should be ultimately as separable as possible. I think that's the big difference between a decade ago and today and the ability to have a lot of these machine readable things that are essentially sitting aside the data that I think mean that you have a way of understanding it by either programmatic or human means. It's something that we just didn't have before when it was either embodied only in the record format or, even worse, in the code that was putting stuff in and out of that record.

I think that's one of the big opportunities we have now. You know, I like to point out to people, you know, you just look at the Internet today; nobody created an a priori taxonomy for the Internet, no one came up with a standard way to describe a Web page. There are about a trillion of them out there now, maybe more. They just keep evolving and that isn't to say that they're good for everything or that you could just say, hey medical things should be done the same way, but allowing that kind of growth in the way the data is out there. Then finding a way to retrofit more and more structure on top of it I think is going to be a good thing over time.

Carl Gunter – University of Illinois – Professor
Okay, I think you've answered this next question, but I just want to be sure. Right now, if you look at search engines—and I understand we're talking about a closed community here—but if you look about search engines the fundamental secret sauce they compete on is how good they are at applying inferencing about what the person really wants to see, finding some ways to take the mixture of text and gobbledygook that's HTML and decide whether Chicago is a rock band or a disease or, I mean, a city, well, most rock bands sound like diseases, but that's their secret sauce; that's the competitive thing they don't share. How do we do that differently and yet get that drive towards innovation that's been the characteristic of the development of Bing and Google today?

Craig Mundie – Microsoft – Chief Research and Strategy Officer
Well, one I guess I'm not sure how much of it isn't shared insofar as there are quite a few companies who have built a variety of search engines. There's the biggest ones that you know about; you know, I saw a company just last summer who started from scratch, you know, wrote a search engine. Their product was to basically index the metadata that described all the products that they could find on the Web so that you could compare parameters of Ford Taurus with a Chevy Volt or something if you wanted to do it programmatically.

So, the other thing is that even if you look at the search engine providers, Google and Microsoft, at least those two that I know about, they actually sell the search technology for people to use inside their firewall and it's largely derived from the same capabilities. It doesn't have to deal with the same scale, but some of the secret sauce is packaged up in these appliances that people are applying internally. So, I think if

you look around the world at the number of people doing it and you look at the scale and the context and how much here I'll say is more explicit about what you're trying to understand as opposed to implicit in the case of the general Internet search I think there are ways to access that technology.

Carl Gunter – University of Illinois – Professor
Thank you. Okay, so Eileen.

Eileen Twiggs – Planned Parenthood Federation of America – Director
I really want to thank you for I think you guys have put out some really I like to think of them as big, hairy, audacious goals. I'm not sure whose phrase that is, but I'm going to borrow it for a minute and I think that innovative uses of technology always identify areas for needed reform and so I think clearly that's part of the conversation that we've had today. I think one of the things that we're really struggling with is time frames and I know in the Report you say that ONC and CMS should focus in 2013 and 2015 on more comprehensive ability to exchange information. But you also then say that given the complexity for this sort of vision that you've painted that you really need to take an incremental approach.

So, I have a couple of questions just in terms of what I've heard today. So, it seems like we have some issues of market preparedness in terms of patients' ability to participate in terms of providers' ability to actually institute a chain of trust and payment reforms and incentives and all sorts of things that really need to happen in order to make these goals achievable. And one thing about technological innovation is that reform usually lags behind it, particularly legal and regulatory reform and it catches up. But given the potential for harm in this situation that we're talking about to patients in terms of privacy, I'm just wondering in your deliberations, did you actually put a timeline on when you thought the big, hairy, audacious goal was really achievable? So, is this a 20-year plan that we can start in the next two years? Is it a ten-year plan? I would be interested to understand, given all of the moving pieces here that need to happen when you think these goals are really achievable?

Christine Cassel – ABIM and ABIM Foundation – President & CEO
Let me just say a couple of things. We didn't put a date on it because anybody who deals in the technology world who tries to predict how long anything is going to take to happen is going to be wrong, so some of this is to make these forces possible to evolve. The one thing that we did know and actually our friends from ONC really emphasized is that the current pace of adoption and use of electronic information with just the incentives that ONC has to work with is not sustainable. Once that money goes away a lot of these doctors are not going to keep using this, if it doesn't become more fluid and more a part of the language that they all use, if you want to think about it that way. So, that's why we were pushing the meaningful use milestones, which are 2013 and 2015, to find a way to get a foot in the door, that first step and we have some ideas about what that might be.

Craig Mundie – Microsoft – Chief Research and Strategy Officer
Yes, I had meant to comment earlier and forgot to, but it addresses your question directly. In the course of the day there were a lot of discussions about well, we should go slow or we should do a lot of pilots and study this stuff. The reason that we made the recommendation the way we did is one, we felt that we did have a fairly unique opportunity in the current macroeconomic environment to try to take some of the monies that were already allocated in these second and third tranches and at least steer them a little bit in a direction that would move us to this, I'll call more generalized model of exchange as opposed to the current just report these specific items for meaningful use.

So, one way to think about—and I'll say I guess the way we would think about—how this evolves is not that you pilot it by saying, oh, let's go over to this hospital or this state or something and do it. But rather that you start and say, look, the general model is we're going to create this indexing or access control system. We're going to put some identities in place and we're going to basically say we want people to publish to the index, in other words, at the boundary of their organization, a very small number of data elements.

So, I think today a lot of the discussion tended to seem like, wow, I've got to get this metadata attached to every data item in my hospital in order to get going. In fact, our view was exactly the opposite. I could

argue that if you said I've got a DEAS, a subset of the people in the country who I'm going to issue credentials to and a set of hospitals, maybe all of them, who want to participate in meaningful use can opt in and say just as meaningful use selected, in the first version, selected just a few things that you had to send in to qualify, instead of thinking that you send in these things. What you're going to do to get this system going is you say, okay, we've identified something, maybe just one thing.

Christine Cassel – ABIM and ABIM Foundation – President & CEO
Medications.

Craig Mundie – Microsoft – Chief Research and Strategy Officer
Like, medications.

Christine Cassel – ABIM and ABIM Foundation – President & CEO
Allergies, immunizations are three good examples today.

Craig Mundie – Microsoft – Chief Research and Strategy Officer
They were all mentioned today, and say okay, take that, 2013 the meaningful use goal is to basically say if you want to participate and get the money what you have to do is take that stuff, you have to annotate it. Put it in this form, this XML defined container that we're going to give you and you have to register your organization with the indexing system and let it crawl your data and put it in the index.

Now, at that point, somebody can write an application; it will take it from there and send it in so that it's an alternate way of satisfying the goals of meaningful use. The difference is instead of each company doing an ad hoc way of sending it in to get the money, as we did in the first generation, what you're really doing is say to participate what we're forcing you to do is to build the mechanism to be able to take something that's hidden in your current clinical system, annotate it and place it someplace where this registered indexing service can find it and index it.

In doing that, you could call it a pilot because it's just a tiny thing, but in a sense it's like driving a little wedge. You have this giant thing, you take one little wedge, you drive it all the way through the system to see if you can make the whole thing work. I would argue at that point the cost of an organization figuring out how it's going to take some data it has and put it out in this form is arguably probably not substantially harder than what they've been going through to try to figure out how to extract it. Then push it out under the current meaningful use things. The difference is this becomes a thing where the next time you just say, well, now I'm going to add another one to it or I'm going to have more people do it, and you're basically just building a generalized mechanism as opposed to building a single, selected set of ad hoc exchanges.

Then, I generally agree with your statement the best kind of legislation is ex post factor, you know, when things have happened and you know that society doesn't like them, like all the current discussions about Internet privacy. You know, there's enough history, people saying, well, there are some things I like and some things I don't like so the Congress is contemplating putting some rules in place.

In this case, we felt that there were some thing that probably had to be put in place preemptively if you wanted to have trust on the part of the consumer. In our case we thought of that quite narrowly as it relates to, if you will, how does HIPAA have to be evolved in order to deal with this environment. What are the kinds of regulations and penalties associated with violation of those regulations that make people believe that you're serious about working in this context and that people who abuse that privilege in any way are facing a serious set of legal problems. I do think that some of that may have to be done preemptively and we encourage ONC to think in their regulatory capacity and in conjunction with the Congress whether or not that kind of thing should be put in place narrowly, specifically as it related to the concern over trust on privacy.

Eileen Twiggs – Planned Parenthood Federation of America – Director
Thanks. I just want to clarify; I don't actually necessarily agree that the best forms of legislation have happened ex post facto. I just think it's the fact of how the sort of regulation of Internet behavior has

occurred over the years and I'm not sure that we're in a position, given the exchange of this sensitive information to actually allow that to continue.

Craig Mundie – Microsoft – Chief Research and Strategy Officer
Yeah, that was probably the wrong word; in general, things that relate to technology are too hard to anticipate to write the laws ahead of time. But in this case, there's enough history with other privacy issues and it's so central to the question to share or not to share here, that it may be appropriate at least by regulation to make it clear that there's real seriousness around this.

Carl Gunter – University of Illinois – Professor
I guess a general question here is what's the sustainability model for this? So, when we need funding for the DEAS and meaningful use is gone, what do you have in mind?

Craig Mundie – Microsoft – Chief Research and Strategy Officer
Well, to be clear we didn't suggest that DEAS should be funded through the meaningful use money.

Carl Gunter – University of Illinois – Professor
I know, but you didn't suggest what the DEAS would be funded by I don't think.

Craig Mundie – Microsoft – Chief Research and Strategy Officer
Well, I think in the report we actually did say that the president felt. I think we all felt that one of the reasons to do this is that the country has to move onto some strategy that's going to alter the fundamental cost equation and so our view was if you get this thing bootstrapped. In fact, it does provide a way, for example, of moving to an alternative payment architecture, there's a lot of talk about moving to ACOs, for example, but almost any shift away from the current fee for service arrangement requires that you have something else you can measure, like outcomes. Unless you can have a near real time view of the entire patient and do that against a population view of similar problems, I don't think you can believe you've got a sustainable way of defining what those outcomes are and whether they're being adequately delivered.

So a big part of doing this at the president's request was not to deal with the access issue so much as the interplay between outcomes and cost and so I would tell you that the sustainability economically comes from the fact that if this turns out to be a key prerequisite to altering the fundamental payment architecture. Then as the incentives essentially get shifted around and efficiencies are recouped, then part of the recoupment should actually pay for the sustaining element of this particular part. I guess the other thing is in a GDP the size of this one and with 16.5% or whatever it is this year going to healthcare at large, if you look at even the biggest companies who make the world's biggest search engines and other things for the entire Internet. Look at their entire corporate budgets to do these things, they're a pittance in the grand scheme on what the country spends on healthcare.

So, I mean, if you just use that as a reasonableness measure, you can say, well, they're doing something a lot bigger in absolute scale than we're talking about doing here, and they're doing it one company at a time on their own nickel, based on their own revenue and R&D budgets. So, it's just sort of a wild assed way of gauging is this something that the country could afford to sustain if, in fact, it's the harbinger of a way to save costs?

Carl Gunter – University of Illinois – Professor
So, Paul, I'll summarize and then I guess we switch. So, just to summarize some of the high points as I heard them; there will be a period of public discussions, so you may get a chance yet and we switch to that next. Sorry about that. So, a few high points; first of all, no one with a business model for being the DEAS should be the DEAS is one of the things that's been urged here. The DEAS technologies could draw on machine learning and corporate search and experience with general search in other context, the hope being that those lessons can be effectively applied in this particular area. We should aim for modest achievable goals with meaningful use incentives to try to bootstrap the system and if we achieve some of the basic goals that are hoped for in terms of changing fundamentals, the payment system, then the means to pay for this and sustain will be the least of our worries.

Paul Egerman – Software Entrepreneur
Great summary. I'm actually going to ask a question; I was curious. I wasn't sure I understood your answer to Eileen's question because the very first recommendation that PCAST made says move more boldly to ensure the nation has electronic health systems and then it says to signal now that systems will need to have this capability in order to qualify for the 2013 Stage 2 meaningful use.

My question is, maybe I didn't understand your answer—but my question is there was a lot of discussion today that before we go forward with the DEAS part, which is an interesting and novel concept, there needs to be some pilot testing. What is your view of that? Should we do pilot testing or should we have like a DEAS structure without any pilot testing as part of the stage two of meaningful use?

Craig Mundie – Microsoft – Chief Research and Strategy Officer
Yeah, I tried to answer by saying it's my personal opinion that you should build an end-to-end system and limit the amount of data that you put into it. So, you can say it's piloted only in the sense; in my mind there's no issue of piloting relative to scale. I don't see, personally, any technical reason to think that you've got a big scale problem here. But there are many people who have to adapt a lot to ultimately say well, I want everything to work this way. So, our view was the way you get started was to build, I'll call it and end-to-end instance for all people who choose to participate by using the meaningful use second and third tranches as a way to incent them to make the data available as part of this complete end-to-end system. So, you're controlling the risks by controlling how many people participate, what data you choose to put into this architecture in the beginning and in trying to put that all in place, I think you'll learn a lot more than trying to take and build a more comprehensive installation, but only in one place or a very small pilot. So, that was sort of our model.

Paul Egerman – Software Entrepreneur
In calling who is participating you're still saying everybody who is doing stage two has to publish something like medications to a DEAS, is that what you're saying? Is that what you're saying?

Craig Mundie – Microsoft – Chief Research and Strategy Officer
Yeah.

Paul Egerman – Software Entrepreneur
Even though we don't have any specification for DEAS right at this moment or governance for it?

Craig Mundie – Microsoft – Chief Research and Strategy Officer
Yes.

Christine Cassel – ABIM and ABIM Foundation – President & CEO
Or it could be an option, part of the menu.

M
Well, he's asking where are you going to get a DEAS I think.

M
That's right.

Craig Mundie – Microsoft – Chief Research and Strategy Officer
I'm saying I don't think they're that hard to build. I've seen start-ups build one big enough to do what I just described with a handful of guys in about seven or eight months, so you can make the thing more and more scale capability. What's important is to get the architecture bootstrap and then make every element of the implementation more and more robust over time. You could probably go buy a commercial enterprise grade search appliance for the scale of what you would do in the next few years and then bolt some stuff around it to create the appearances of the controls you want on the access part. I mean I'm just speculating now, but to get going it seemed to be a lot more important to get people to try to operate within that architectural frame. Than it is to get one or two people to try to do a lot within that frame and the learnings that will happen there then allow the whole thing to continue to grow.

Each generation of implementation can get more robust; you can get some sensitive data, you can include more people, you can add rolls. I view all that as something that can be done stage by stage, but that in each case you're taking the general architectural model and embellishing it over time as you learn about what's good and bad about the system overall and learn about what the specific implementation challenges are as you try to move each aspect of it to be more comprehensive. But if it was my choice I would basically say it's better to get everybody who wants to participate in the second round and third round of meaningful use to take their toe and stick it in the water of this architecture than it is to say I'm just going to keep doing more of the same. So in that regard, it was what we called move boldly at the beginning.

Paul Egerman – Software Entrepreneur
I appreciate that and I appreciate it is moving boldly. I look at this as a situation where there's really no industry example, in my opinion, of the entire combination of the universal exchange language in this sort of searchable database that's interlinked with it. So, you say it's moved boldly; I think you're telling us to boldly go where no one has gone before. Pardon me?

Christine Cassel – ABIM and ABIM Foundation – President & CEO
With legality and privacy issues that are pretty strong.

Paul Egerman – Software Entrepreneur
But anyway, I appreciate your comments. Now we have time for the public comments, so I hope that people will make some comments. I do want to tell everybody that at 8:30 tomorrow morning we will be – pardon me? What time is it tomorrow morning?

M
Nine.

Paul Egerman – Software Entrepreneur
At 9:00 tomorrow, sorry, we will resume. Are we in this room? Someplace here. Somebody is raising up their hand; is that something I need to know, or these are the people who want to do the public comment. So, Judy will tell you how to do the public comment.

Judy Sparrow – Office of the National Coordinator – Executive Director
Public comment now. If you wish to make a comment from the room there's a microphone. Dr. Peel.

Deborah Peel – Patient Privacy Rights – Founder & Chair
Craig, I was really shocked about you saying that the system that you envision is a closed system with only authorized users. That's what we have today. We have over four million authorized users who take the information, send it to second and third and so on parties and we have no control, so I'm puzzled about how your system would actually be closed. I mean, it sounded to me like what we have now, which is a situation that's created all the commercial use of data and the misuse of data.

Judy Sparrow – Office of the National Coordinator – Executive Director
They're comments, you don't really need to answer. Duly noted. Next.

Imran Chadry – Afixia
Hi, this is Imran Chadry from Afixia. Just want to say that with semantic search you can actually harmonize ad hoc and discrete data and that is available today. The other thing, I'd like to I guess throw out a question is, from my experience and looking back at Internet history, I really haven't seen any examples of a large publicly supported DEAS like system, and I think we've really got to find an analogy before we can proceed strongly with this idea.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. Tim.

Tim McNamara – e-service
Paul, the industry-wide example you're looking for is ATMs. The reason they work is because they have one data standard. I would suggest that people keep in mind that XML is a generic term like airplanes. It covers what the Wright Brothers flew at Kitty Hawk, the DC-3, the Concord, the J-20 and they all have different capabilities. XBRL is just a later generation of XML and it can be adapted very easily to healthcare. The semantics have been done by the SDOs and all you have to have is the tagging software, but it does cost $285 to go from XML to XBRL and you can get things done very quickly. It's not expensive, it's not hard.

Bob Rogers – Apixio
Hi, I'm Bob Rogers. I'm Chief Scientist at Apixio. We're a clinical search engine and I actually wanted to ask a question to clarify the role of universal exchange language in privacy. I'm going to start with an assertion that in the case of structured data privacy can actually be managed by semantic search using the semantic clinical information that's already there and that gives you the ability to extract privacy appropriateness at a very granular level. For unstructured data, again, I think the only way you can apply privacy restraints is through some sort of semantic analysis or semantic search. So the question that I have is what is envisioned that the universal exchange language would add at the granular data meta tag level that would actually go beyond what we are currently doing with semantic search?

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. And Peter.

Peter DeVault – Epic Systems – Project Manager
Hi, Peter DeVault, Epic. One thing that didn't come up much today and I'm hoping it will in subsequent conversation is the issue around where the industry has already been told to go over the last several years in the use of the HL-7 reference information model, the CDA mechanisms for data format and metadata tagging. It became clear today that the PCAST recommendation is not to rip and replace systems, but I'm still concerned that it's meant to rip and replace standards. So, I'd like to have a discussion about where those standards and information models fail us today in the development of a universal exchange language.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. Any other comments?

Ken Pool – Oz Systems
One request for clarification; Ken Pool with Oz Systems. One of the things that I heard throughout the day today was particularly about the exchange of data, systems exchanging with each other, but it was my original understanding of the PCAST spirit that it intended to eventually create a unified patient record that was accessed rather than exchanged. So it didn't become a process of me exchanging data with you, but rather us contributing to a system that contained the patient record in its virtual entirety and access that and the distinction was confusing for me through the day whether people were talking about exchanging or accessing.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. We have nobody on the phone. Anybody else in the room? Okay, with that I'll turn it back to Paul Egerman.

Paul Egerman – Software Entrepreneur
Thanks, again, and thank you, again, Craig. I appreciate your participating today and you'll be here tomorrow also. So, again, we're resuming at 9:00 tomorrow morning. Thank you very much.